

MARCH 15, 2018 P.M.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re: Bard IVC Filters,)
Products Liability Litigation)
)
) MD-15-02641-PHX-DGC
)
Sherr-Una Booker, an individual,)
) Phoenix, Arizona
Plaintiff,) March 15, 2018
v.)
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral) CV-16-00474-PHX-DGC
Vascular, Inc., an Arizona) 12:59 p.m.
corporation,)
)
Defendants.)
_____)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 2 P.M.

(Pages 337 through 444)

Official Court Reporter:
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United States District Court

MARCH 15, 2018 P.M.

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I N D E X**TESTIMONY**

WITNESS	Direct	Cross	Redirect	Recross
MURRY R. ASCH, M.D	345	366	387	
ALEX TESSEMER	402			

E X H I B I T S

Number		Ident	Rec'd
553	Asch Deposition, 05/02/2016 - Exhibit 203 - 9/14/2002 Memo from Thomas Kinst to Recovery Filter Design History File Re. Recovery Filter Compassionate Use, Subject: "Conference call with Bard Peripheral Technologies regarding clinical assessment of Recovery Filter removal #5"	353	354
555	Asch Deposition, 05/02/2016 - Exhibit 205 - 2005 article by Asch and Cheung et al., entitled "Temporary inferior vena cava filter use in pregnancy"	382	
557	Asch Deposition, 05/02/2016 - Exhibit 208 - 8/28/2000 E-mail from Paul Stagg to Cavagnaro, Mellen, Uelmen, Vierling, and Field Re. "Fwd[2]: compassionate IVC filters (from Asch)",	375	376
558	Asch Deposition, 05/02/2016 - Exhibit 209 - Article by Dr. Murray Asch, entitled "Initial Experience in Humans with a New Retrievable IVC Filter"	379	
559	Asch Deposition, 05/02/2016 - Exhibit 210 - 4/17/2002- Email from George Cavagnaro to Doug Uelmen and Carol Vierling, dated April 18, 2002	361	362
567	Asch Deposition, 05/02/2016 - Exhibit 223 - 3/10/2003 Letter from Dr. Asch Re support for RF	385	

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E X H I B I T S (Continued)

Number	Ident	Rec'd
760 Carr Deposition, 11/05/2013 - Exhibit 07 - NMT Medical's 9/1/2000 R&D Technical Report, No. RD-RPT-128, entitled "Investigation Report of a Migrated Recovery Filter in the Human Use Experience at [Redacted]"; unsigned by Robert Carr, Program Director	346	
925 (Not identified or used)		401
927 (Not identified or used)		401
931 (Not identified or used)		401
1006 DeCant Deposition, 05/24/2016 - Exhibit 254 - 12/9/2003 Meeting Minutes Memo from Brian Hudson to Len DeCant, Mike Casanova, Robert Carr, and Alex Tessmer Re. "Special Design Review for Recovery (Project #'s 7081 and 8008)"	409	409
1216 (Not identified or used)		401
1221 (Not identified or used)		401
1369 Hudson deposition, 01/17/2014 - Exhibit 16 - 3/24/2004 E-mail from Alex Tessmer to Charlie Benware and Ed Fitzpatrick Re. "Starguide Filter Migration Test Results"	434	440
2059 Tessmer Deposition, 06/12/2013 - Exhibit 02 - Project Status Report Form for the Recovery Filter, Project No. 7081, initiated 7/1/2002 with the goal to "Investigate Migration"; FM0700160, Rev. 1.	416	417
2061 Tessmer Deposition, 06/12/2013 - Exhibit 05 - 2/4/2004 E-mail from Alex Tessmer to Several Re. "Updated: Filter Migration Flow Loop Test Fixture"	418	419

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E X H I B I T S (Continued)

Number	Ident	Rec'd
2063 Tessmer Deposition, 06/12/2013 - Exhibit 08 - 2/25/2004 E-mail from Alex Tessmer to Robert Carr and Brian Hudson Re. "Filter Migration Test Results	420	422

MISCELLANEOUS NOTATIONS

Item	Page
Proceedings outside the presence of the jury	342
Deposition Instruction read to jury	395

RECESSES

	Page	Line
(Recess at 2:32; resumed at 2:47.)	399	14

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P R O C E E D I N G S

(Court was called to order by the courtroom deputy.)

(Proceedings begin at 12:59.)

THE COURT: Please be seated.

Mr. Lopez, you wanted to raise an issue?

12:59:26

MR. LOPEZ: Yes, Your Honor. There are two exhibits, one that I intend to offer that makes reference to the Simon Nitinol filter and one that counsel intends to offer I think in his cross-examination and I'm going to object to the document as being beyond the scope. Both documents make reference to the Simon Nitinol filter having a 14 percent fracture rate I think it is and then this one that talks about the migration that happened in Dr. Asch's study references also I think a clinical trial or something as it relates to the SNF. I've got CMO10, I think it's 10, where we wanted discovery on the Simon Nitinol filter, specifically the --

12:59:43

01:00:15

THE COURT: Hold on, Mr. Lopez. I don't want to keep the jury waiting about issues we could have talked about earlier. They are assembled waiting to walk in here. Is this going to require me to go back into that --

01:00:34

MR. LOPEZ: Well, I'm sorry, Your Honor. I didn't let you finish asking your question.

THE COURT: Well, do I need to go back and look at case management orders?

MR. LOPEZ: I have it right here.

01:00:46

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1 THE COURT: Well, I don't want to keep them waiting
2 for more than a minute. When are you intending to raise this
3 issue?

01:00:47

4 MR. LOPEZ: I'm going to put this document that --
5 I'm going to put in but I want to redact a portion of it that
6 was consistent with CMO10.

01:00:54

7 THE COURT: So you wanted to introduce the document
8 and redact a portion of which you are presenting?

9 MR. LOPEZ: Well, maybe I just won't offer the
10 document. I'll just use to it refresh his recollection.

01:01:08

11 THE COURT: Well, I'm just trying to understand what
12 the issue is. Is it that you want to present a redacted
13 document and the defendants don't want you to?

14 MR. LOPEZ: No. In the document, it references
15 information about the Simon Nitinol filter that we wanted to
16 get discovery on and they objected to and we have a CMO that
17 says that we can't have it. So I don't know how to handle it
18 other than the fact that it would be unfair now for them to
19 introduce evidence through a document or otherwise about the
20 Simon Nitinol filter's clinical performance when we didn't get
21 any complaint files. They objected to us getting all of that
22 and now they are going to get in through a hearsay document,
23 you know, percentage of the fracture. We would have loved to
24 have seen the --

01:01:19

01:01:43

25 THE COURT: Okay. I understand your point.

01:01:57

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1 What were you going to say in response? 01:01:58

2 MR. NORTH: Your Honor, I really don't understand
3 what's going on. I have not been consulted about this
4 beforehand. I'm not even sure what documents he's talking
5 about. I'm certainly willing to -- 01:02:05

6 THE COURT: You ought to confer before raising these
7 issues. I'm not going to rule on it now. What you can do is
8 you can use the document to refresh his memory. If you want to
9 put it in and not show it to the jury and we can argue about
10 redactions later, we can do that; but I don't want to keep the 01:02:24
11 jury waiting while we address an issue that you haven't
12 conferred about or that requires further reaching, so we'll go
13 ahead and bring the jury in.

14 Mr. Lopez, you can raise that at the start of the
15 break or at the end of the day. I'll be happy to talk to you 01:02:56
16 about it.

17 MR. LOPEZ: I apologize, Your Honor. I should have
18 raised it this morning.

19 THE COURT: That's all right.

20 (Jury enters at 1:03.) 01:03:25

21 THE COURT: Please be seated.

22 All right. Ladies and gentlemen, we're going to
23 continue with testimony of Dr. Asch.

24 Mr. Lopez, you may continue.

25 MR. LOPEZ: Thank you, Your Honor. 01:03:48

United States District Court

MURRY R. ASCH, M.D - Direct

1 (MURRY R. ASCH, M.D., a witness herein, was duly
2 sworn or affirmed.)

01:03:49

3 **DIRECT EXAMINATION** (Continued)

4 BY MR. LOPEZ:

5 Q. Okay. Dr. Asch, let's now talk about the actual pilot
6 study that you performed. Was this performed at one location?

01:03:52

7 A. It was performed at a number of locations. The radiology
8 group that I belong to serviced a number of hospitals in the
9 downtown corridor all within a few blocks of each other. So
10 there were three or four different institutions under one
11 umbrella.

01:04:14

12 Q. And while you were in the course of monitoring the
13 patients that were in the study, did you take radiographs of
14 them as we had seen in an earlier document so you could monitor
15 the device itself?

01:04:35

16 A. Yes. Radiographs were routinely obtained and in addition
17 to the radiographs that were obtained as part of the study,
18 because I wanted to keep a close eye on these patients, many of
19 them were in hospital and ill and had CAT scans and radiographs
20 for other reasons. So I would personally review all of those
21 studies again to be sure that they were being as closely
22 monitored as possible.

01:04:51

23 Q. And Dr. Asch, during the course of this study, did you
24 have a patient whose Recovery filter was challenged by a clot?

25 A. Yes, there was.

01:05:09

United States District Court

MURRY R. ASCH, M.D - Direct

1 Q. And was it the type of clot that the device was designed
2 to prevent from moving the device beyond where it was inserted?

01:05:10

3 A. Yes. An IVC filter, in my view, should be able to trap
4 any size clot and yet remain stable in position.

5 Q. Okay. What happened to the very first patient in your
6 study whose Recovery filter was challenged by a large clot?

01:05:29

7 A. Well, fortunately, as I say, because I was monitoring
8 these patients, I discovered that his IVC filter had migrated
9 even though it hadn't been reported by the diagnostic imaging
10 radiologist who was reading those radiographs. So as soon as I
11 discovered that, after a few phone calls and thinking, then we
12 made arrangement to have the filter removed for fear that once
13 it started to migrate, as soon as it moves we'll call it north
14 towards the heart, the cava gets wider at that point in the
15 patient's body. So the risk of migration would be even higher
16 so as soon as I noted that, I acted on it immediately.

01:05:54

01:06:17

17 Q. Do you have any recollection as to whether or not the
18 device moved caudally before it moved towards the heart?

19 A. I don't recall that it moved caudally. The most important
20 factor in my mind is that it moved cranially towards the heart.

01:06:38

21 MR. LOPEZ: Could we have Exhibit 760, please, and
22 just show it to Dr. Asch.

23 BY MR. LOPEZ:

24 Q. And Dr. Asch, do you recognize this report?

25 A. Yes.

01:07:01

United States District Court

MURRY R. ASCH, M.D - Direct

1 Q. Is it the investigation report of the migration that we're 01:07:02
2 talking about?

3 A. Yes, it is.

4 Q. If you go to page three of this report, if you look
5 underneath the images, the pre-insertion and post-insertion 01:07:18
6 images, does this help refresh your recollection that this same
7 patient actually had a caudal filter migration?

8 A. Okay. I see that it says that, yes.

9 Q. Okay. And then was it after that -- caudal meaning it
10 moved down first? 01:07:42

11 A. Correct.

12 Q. And is that evidence of instability of the filter?

13 A. Yes. Any movement is evidence of instability. The filter
14 should stay where its put.

15 Q. And then later you discovered that the device had moved 01:07:57
16 towards the heart; correct?

17 A. That's correct.

18 Q. And when you say four centimeters beyond where it was
19 originally inserted?

20 A. Yes, correct. 01:08:06

21 Q. Now, just from the distance from where it was inserted to
22 where the heart is located, so how far from the heart was this
23 device when it was found?

24 A. It's going to vary in different people but let's say four
25 inches, three inches. 01:08:21

United States District Court

MURRY R. ASCH, M.D - Direct

1 Q. Okay. But it was -- it originally moved down and then
2 when you looked at it next time, it was moving up?

01:08:23

3 A. Yes.

4 Q. Did that concern you?

5 A. Yes, very much.

01:08:30

6 Q. Okay. Was there a meeting and discussions among the
7 people from Bard and NMT and even Dr. Kaufman about that, about
8 this?

9 A. Yes. I think as I recall what happened, we planned on
10 removing it because we were concerned about migration. I think
11 what happened later, the meeting was after the initial attempt
12 at removing it when I discovered that there was a big clot
13 there. Now we were faced with how do we deal with a migrated
14 filter that has a large clot in it because this is the first
15 time that we had been faced with a situation like that. So
16 initial plan was filter moved, let's get it out, complicated by
17 some new information. Now filter's all full of clot. What do
18 we do in order to safely get it out?

01:08:50

01:09:08

19 Q. And if you look at page, the Bates number is 545, page six
20 of seven of the document, do you recall there being a meeting
21 among folks from NMT and Bard about this migration?

01:09:26

22 A. I'm sorry. A meeting at the time or afterwards?

23 Q. The follow-up communication where you're looking at on the
24 document regarding this observation of a migration.

25 A. Yes. So there were -- there was discussion and meetings,

01:09:53

United States District Court

MURRY R. ASCH, M.D - Direct

1 telephone conversations and electronic communication between
2 the people involved in the study in order to figure out what do
3 we do going forward from here.

01:09:58

4 Q. And what did you do at that point? What was the decision
5 with respect to the pilot study?

01:10:12

6 A. Well, the decision was to have the NMT people look at the
7 device and see if there was any obvious reason or look at --
8 review patient records and radiographs to see if we could
9 identify what caused the filter to migrate in order to be aware
10 of what the likely risk would be in subsequent patients; and
11 after all of those discussions, we felt as a group that we
12 should continue using close monitoring and continue placing
13 these devices.

01:10:34

14 Q. Was the study at least stopped pending some additional
15 steps to take to protect the rest of the patients in the study?

01:10:53

16 A. Yes. It was stopped temporarily while there could be
17 information gained, as I say, with respect to the filter and
18 patient factors.

19 Q. Was Dr. Kaufman concerned about this incident?

20 A. Yes. I think we all shared similar concern, yes.

01:11:08

21 Q. And what was -- do you recall Dr. Kaufman's concerns that
22 he expressed to you and the folks at Bard and NMT?

23 MR. NORTH: Objection, Your Honor. 802.

24 THE COURT: Sustained.

25 MR. LOPEZ: Exception, Your Honor. Notice, effect on 01:11:31

United States District Court

MURRY R. ASCH, M.D - Direct

1 the defendants' reactions to that information.

01:11:33

2 THE COURT: These are communications to the defendant
3 you're asking for?

4 MR. LOPEZ: It's Dr. Kaufman was at the meeting with
5 Bard and NMT folks.

01:11:45

6 THE COURT: Mr. North seems to disagree that there
7 was such a meeting. Well, let's tie it down to specific
8 communications that you believe were directed to the defendant
9 and if so, I'll give the jury instruction on limited admission.

10 BY MR. LOPEZ:

01:12:02

11 Q. So this meeting that took place, without looking at the
12 document, do you recall who was at the meeting? And if you
13 need to look at it to refresh your recollection, you're allowed
14 to do that.

15 A. I don't actually remember the specifics where the meeting
16 was or who attended the meeting. My main recollection was that
17 there was a number of telephone conversations between several
18 of us. My main conversation was with Dr. Kaufman to try and
19 get a sense, as I say, of how do we decide whether or not to
20 proceed.

01:12:14

01:12:34

21 Q. And if you look at page seven of seven, does this help
22 refresh your recollection as to what the decision was going to
23 be if there was another migration that occurred that would be
24 greater than two centimeters?

25 THE COURT: You're asking him to look at the document

01:13:00

United States District Court

MURRY R. ASCH, M.D - Direct

1 and then see if it refreshes his memory?

01:13:02

2 MR. LOPEZ: I withdraw that, Your Honor. It's not a
3 proper question.

4 THE COURT: All right.

5 BY MR. LOPEZ:

01:13:09

6 Q. Do you recall whether there was any decision among the
7 group what would happen if there was another migration of at
8 least two centimeters with another filter?

9 A. Yes. So the decision was that the study would be stopped.
10 Again, being early on in the experience, and only this was
11 patient number nine, so we didn't really know did this
12 represent -- what true percentage of complication this
13 represented.

01:13:27

14 So we thought we could accept this at that point but
15 if the event was to occur again, that would raise significant
16 concerns that this was a trend rather than I'll call it an
17 isolated event. So, yes, the plan was to look very carefully,
18 follow up all of our patients even more carefully and not
19 tolerate any subsequent migration.

01:13:41

20 Q. Did the discussion include Bard and NMT looking at
21 redesigning the device?

01:13:59

22 A. At that point, I don't recall there was discussion about
23 redesigning the device because it was not communicated it to me
24 that any design factor was at fault here.

25 Q. I am going to try to refresh your memory about that on

01:14:22

United States District Court

MURRY R. ASCH, M.D - Direct

1 page seven of this document that has been marked as an exhibit. 01:14:25
2 The first sentence there. Does that help refresh your
3 recollection as to whether or not there would be a reevaluation
4 of the filter design?

5 THE COURT: So the question Doctor is, after you read 01:14:37
6 that sentence, is your memory refreshed? And if so, you can
7 testify from your memory.

8 THE WITNESS: I'm not certain which sentence.

9 BY MR. LOPEZ:

10 Q. The very first sentence in the end, "Everyone agreed." Do 01:14:48
11 you see where I am?

12 A. Okay. Yes.

13 Q. Read that and does that helps refresh your recollection
14 that the discussion or the agreement include a filter --
15 reevaluating the filter design? 01:15:00

16 A. Yes, exactly. So if the event occurred again, then the
17 study would stop and they would re-evaluate filter design, yes.

18 MR. LOPEZ: Per our discussion, I'm going to reserve
19 moving that document into evidence at this time.

20 BY MR. LOPEZ: 01:15:25

21 Q. Okay. If you look at -- let's put up 533. 533 is a memo
22 dated September 14, 2000, from Thom Kinst; and if you look at
23 it, you're not on the cc of that. Do you see that, Dr. Asch?

24 A. Yes.

25 Q. But if you look down four paragraphs, it does mention you 01:15:45

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MURRY R. ASCH, M.D - Direct

1 as being involved in the conference call that is referenced in
2 this email. Does that refresh your recollection that you were
3 involved in the conference call that is described in this
4 document?

01:15:48

5 A. I can't see the document from here. I do clearly recall
6 that I was involved in conference calls regarding the
7 migration.

01:16:00

8 Q. Look at -- okay. I want to make sure we have it in
9 relationship to this document. The fourth paragraph?

10 MR. WOODY: Start over with which document?

01:16:17

11 MR. LOPEZ: 533. Did I say it wrong?

12 MR. WOODY: What's the Bates number?

13 THE COURT: Folks, while they are doing that,
14 somebody in the courtroom has your cell phone on. Would you
15 please turn them all off? Having them just on mute doesn't
16 help. We still get interference with the sound system. Or put
17 them on airplane mode. That also would work.

01:16:48

18 MR. LOPEZ: My apologies, Your Honor. It was
19 actually 553. Can we have 553, please.

20 THE COURT: Is 553 the December 14, 2000, memo,
21 Mr. Lopez?

01:17:52

22 MR. LOPEZ: Yes, sir.

23 THE COURT: Okay.

24 BY MR. LOPEZ:

25 Q. Okay. Now we can look at the fourth paragraph of the

01:18:02

United States District Court

MURRY R. ASCH, M.D - Direct

1 right exhibit where it mentions your name there. Does this
2 help refresh your recollection -- go down four where it says,
3 "Thom Kinst led the discussion."

01:18:06

4 Do you see that, Dr. Asch?

5 A. Yes.

01:18:23

6 Q. And is this a summary of those discussions that you had
7 after you experienced the migration of patient number nine in
8 your study?

9 A. Yes, it is.

10 MR. LOPEZ: I would like to offer this into evidence
11 at this time, Your Honor.

01:18:33

12 MR. NORTH: No objection, Your Honor.

13 THE COURT: 553 is admitted.

14 (Exhibit Number 553 was admitted into evidence.)

15 BY MR. LOPEZ:

01:18:47

16 Q. Okay. If you go to the second paragraph.

17 THE COURT: Do you do want this displayed?

18 MR. LOPEZ: Yes, please publish to the jury. Thank
19 you.

20 THE COURT: All right.

01:18:54

21 MR. LOPEZ: Second paragraph. Present at the
22 conference call.

23 BY MR. LOPEZ:

24 Q. And those are folks from NMT. Do you see that?

25 A. Yes, I do.

01:19:15

United States District Court

MURRY R. ASCH, M.D - Direct

1 Q. And do you recognize there are also folks there from Bard
2 as well; true?

01:19:15

3 A. Correct.

4 Q. And then the third paragraph states: The purpose of the
5 conference call was to inform the Bard group of the conference
6 call from 12 September 2000, the physicians' clinical
7 assessment and NMT's plans in continuing the compassionate use
8 experience with Dr. Asch.

01:19:36

9 Do you see that, Doctor?

10 A. Yes, I do.

01:19:51

11 Q. And then the next paragraph, there's Tom Kinst is
12 mentioned again and he refers to -- he says: Please refer to
13 the memo dated 12 September 2000 recording the conference call.

14 Do you see where I am?

15 A. Yes.

01:20:08

16 Q. And then below that --

17 MR. LOPEZ: Could you highlight that, Greg, and bring
18 it out?

19 Q. Given the compassionate use data to date, it can be stated
20 that the Recovery filter has a 10 percent migration rate.
21 NMT's response was that we suffering from the N, equals sign,
22 one syndrome.

01:20:21

23 What does that mean?

24 A. Well, it basically means that only a single N is the
25 number of events that something occurred. So one event

01:20:40

United States District Court

MURRY R. ASCH, M.D - Direct

1 occurred. But because it was so early in the experience and
2 there were only nine -- this was patient number nine, it was
3 hard to know what true relative risk filter migration held
4 because is it going to occur in one in ten patients or is it
5 going to occur in 10 in 100 patients or more than that?

01:20:43

01:20:58

6 Q. And it says: We cannot conclude if the event is due to
7 Recovery filter design issues, is reflective of the normal
8 migration rate of all filters, or is an idiosyncratic event.
9 Did I read that correctly?

10 A. Yes.

01:21:18

11 Q. And then it states: Only a large, controlled clinical
12 study can definitively assess it.

13 Did I read that correctly?

14 A. Yes, that's correct.

15 Q. And that was an agreement among all the people that were
16 at this meeting?

01:21:26

17 A. Yes.

18 Q. Now, this 10 percent migration rate, let's talk about
19 that. Were there any other patients in your study whose
20 filters were challenged by the type of clot that you saw in
21 patient number nine that put the device at risk of moving from
22 its location?

01:21:39

23 A. No, there were not.

24 Q. So.

25 So really in your study, insofar as the type of clot

01:21:52

United States District Court

MURRY R. ASCH, M.D - Direct

1 that the device was supposed to stop from moving towards the
2 heart, that migration rate was one out of one,100 percent?

3 MR. NORTH: Objection, leading.

4 THE COURT: Sustained.

5 BY MR. LOPEZ:

6 Q. Well, there was only one -- there was one out of one of
7 the devices that were challenged by the -- by a clot that was
8 of the quality that put the patient at risk of maybe a
9 pulmonary embolism; true?

10 A. That's correct.

11 Q. Okay. Let's go to page two, number three -- I'm sorry,
12 number two on page two: Dr. Asch has informed the HPB --
13 that's the regulatory body in Canada correct?

14 A. Correct.

15 Q. -- and Hospital Ethics Board of the event and the
16 compassionate use experience to date.

17 Correct?

18 A. Yes.

19 Q. So you reported this to both the regulatory body and to
20 the ethics board that were involved in this study?

21 A. Yes.

22 Q. Dr. Asch will draft an addendum to the patient consent
23 form summarizing the compassionate experience. This will be
24 similar to the summary sent to the HPB and ethics boards.

25 What did you mean by that?

United States District Court

MURRY R. ASCH, M.D - Direct

1 A. Well, now that we had experienced a complication, we had
2 more new, updated information as to the specifics of this
3 filter and so it's essential to share that information with
4 patients so that moving forward, we can ethically obtain an
5 informed consent because now we have new information. That
6 information needs to be provided to the patients.

7 Q. So in other words, all the other patients in this study,
8 according to the ethics board, had the right to know about that
9 experience so they could make a decision on whether to continue
10 in the study?

11 A. That's correct.

12 Q. And then number three: It was agreed by the physicians
13 and NMT that it is reasonable and prudent to require periodic
14 biweekly abdominal x-rays to monitor the location of the
15 filter.

16 Do you see that, Doctor?

17 A. Yes.

18 Q. And is that what you did throughout the balance of this
19 study?

20 A. Yes.

21 Q. And of course throughout the balance of the study, the
22 device had not been challenged again like it was -- like
23 patient number nine was challenged; true?

24 A. That's correct.

25 Q. And then number four, paragraph four: It was established

United States District Court

MURRY R. ASCH, M.D - Direct

1 that if, one, the filter moved four centimeters, one filter
2 length, or, two, the filter moved in a suprarenal location --
3 what's a suprarenal location?

4 A. So supra is a fancy word for above and renal is a fancy
5 word for kidney so the kidney vessels veins are the standard
6 landmark for where we place filters. We normally place them
7 below the renal veins because above the renal veins, the IVC
8 gets larger. So we discussed before the fact that these
9 filters are meant to go into a cava less than 28 millimeters in
10 diameter. As you get above the renal veins, cava gets larger
11 and, therefore, the risk of migration will be higher because
12 now you've exceeded the requirements for caval diameter.

13 Q. And then when you read past that, the compassionate use
14 experience would be immediately stopped and the filter design
15 challenged. What does that mean, Doctor?

16 A. So again out of concern, if another episode was to occur
17 or an episode where the filter migrated above the level of the
18 renal veins, then we would stop it out of concern for -- that
19 this was a more real and not an unexpected or low-incidence
20 complication. And so that we would then, for patient safety
21 reasons, stop the study, allow the device to be redesigned so
22 that the risk of migration would be reduced.

23 Q. And then it continues: Filter implants would be halted,
24 but filter removals of indwelling filters would continue until
25 all remaining filters were removed.

United States District Court

MURRY R. ASCH, M.D - Direct

1 A. Yes.

01:26:29

2 Q. And that was an agreement among everybody that was
3 involved in this conference call that we've just been
4 discussing?

5 A. That's correct.

01:26:35

6 Q. And then, Doctor, was there also an occasion within your
7 study where one of your patients experienced a filter fracture?

8 A. Yes, that's correct.

9 Q. Would you describe that event for the jury, please.

10 A. So this was a woman who was pregnant and had the filter
11 placed while she was pregnant for standard reasons and it was
12 noted, again, because of monitoring, because she was in the
13 study, she was having radiographs that other patients wouldn't
14 normally have. And during the course of those routine
15 radiographs, it was found that her filter had been fractured.

01:26:51

01:27:10

16 So, again, as soon as I found this, I made
17 arrangements to have the filter removed for fear that with a
18 filter fracture where the filter is unstable and the component
19 or the filter could migrate to the heart.

20 Q. And I think you referred to that as patient number 33.

01:27:34

21 A. That's correct.

22 Q. By the way, let's go back to patient number nine. I mean,
23 this -- I think you said this was the type of clot that, you
24 know, might have caused a PE in that patient?

25 A. Yes.

01:27:50

United States District Court

MURRY R. ASCH, M.D - Direct

1 Q. And we don't know were whether or not it would have been a 01:27:51
2 fatal PE. We just know it was working its way in that
3 location; right?

4 A. Correct.

5 Q. And technically, did that event, at least up to four 01:27:58
6 centimeters, save the patient's life?

7 A. Well, the filter did part of its job in terms of trapping
8 the clot, but the filter failed in that it migrated. And as we
9 know and as we previously talked about, as the filter moves
10 more towards the hearts, risk of migration is higher. And 01:28:21
11 outside of a clinical study where someone is being closely
12 monitored, my concern is that that filter would have ultimately
13 killed that patient.

14 Q. So was it the monitoring that potentially saved this
15 patient from the filter continuing to go to his heart? 01:28:37

16 A. Yes.

17 Q. Okay. Let's look at Exhibit 559, please and 559 is dated
18 April 18, 2002, and do you see it looks like it's a memo that
19 was forwarded that was authored by you? Do you see that,

20 Dr. Asch? 01:29:07

21 A. Yes, I do.

22 Q. And this was an email that you sent to whom? Do you
23 recall?

24 A. I believe it's to HPB, Health Protection Branch, Canada
25 and the Ethics Department as per my requirement as ethical 01:29:27

United States District Court

MURRY R. ASCH, M.D - Direct

1 performance of the research study, I need to report any
2 adverse -- I potentially serious adverse events and this email
3 was part of that reporting.

4 Q. Okay. And do you know who George Cavagnaro is?

5 A. I don't remember his position. He worked at Bard. He may
6 have been Monica's manager but I don't recall specifically.

7 Q. How about Doug Uelmen and Carol Vierling, do you recall
8 those names?

9 A. Carol I believe was part of -- she worked for the head
10 office of Bard. I don't have her exact.

11 MR. LOPEZ: Your Honor, I would like to move 559 into
12 evidence and have it shown to the jury, please.

13 MR. NORTH: No objection, Your Honor.

14 THE COURT: Admitted. You may display.

15 (Exhibit Number 559 was admitted into evidence.)

16 BY MR. LOPEZ:

17 Q. And this is an email -- I'm not sure it's an email but
18 it's something that you write?

19 A. Yes. I think it was an email.

20 Q. Okay. It's your email address.

21 Now, let's look at the first part of that. It's kind
22 of weird because the way it got cut and pasted, it's going to
23 be kind of a struggle to read. It doesn't go in a straight
24 line. I'm going to read it and just let me know whether I've
25 read it correctly, Dr. Asch.

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MURRY R. ASCH, M.D - Direct

1 Starting at the top, this I, meaning you, compelled 01:30:54
2 to report this week's adverse event, RNF fracture to HPB and to
3 our IRB. I have not heard back from Ottawa, however, as
4 expected, the IRB has suspended the trial effectively
5 immediately until the nature of the problem with the device can 01:31:13
6 be better -- until the nature of the problem with the device
7 can be better understood.

8 Did I read that correctly?

9 A. Yes, up.

10 Q. Does that mean the study was stopped? 01:31:24

11 A. Yes.

12 Q. And then if you drop down a little more beginning with the
13 word "hopefully." Well, there's more than one hopefully. I'm
14 sorry. The first hopefully. It's hard to read. It's about
15 five lines down from what you have highlighted right now. 01:32:00

16 And then you write: Hopefully Monday, Monica --
17 Monica is the Bard representative?

18 A. Yes.

19 Q. -- can drop by to pick up the filter so that it can be
20 sent to Atlanta or Boston to be analyzed. Did you have a 01:32:27
21 chance to look at the filter images I sent yesterday? It seems
22 to me that the filter hook broke off at the attachment to the
23 leg.

24 Is that what you reported to Bard?

25 A. Yes. 01:32:42

United States District Court

MURRY R. ASCH, M.D - Direct

1 Q. Hopefully --

01:32:47

2 MR. LOPEZ: Now we can go down to the next hopefully,
3 Greg.

4 Hopefully you can come up with a good explanation for
5 the problem and that it would not be expected to recur.

01:32:59

6 Do you see that?

7 A. Yes.

8 Q. And then you write down two lines: It might be
9 interesting -- it might be interesting to test hooks from other
10 filters.

01:33:22

11 Did I read that correctly?

12 A. Yes.

13 Q. And that's advice or information you provided to people at
14 Bard about the fracture; correct?

15 A. Yes.

01:33:34

16 Q. All right. Did Bard make you any promises or represent to
17 you what they were going to do with respect to the Recovery
18 filter after having experienced this migration and these
19 fractures in your pilot study?

20 A. Yes. So after this fracture occurred, Bard assured me
21 that they would evaluate the filter which was returned to them
22 and NMT to decide could they identify a manufacturing problem
23 or a design issue which then would consult in a redesign of the
24 filter in order to prevent these types of events from occurring
25 again.

01:34:01

01:34:24

United States District Court

MURRY R. ASCH, M.D - Direct

1 Q. Were they specific about the type of design things that
2 they had in mind to make it more fracture- and
3 migration-resistant?

01:34:26

4 A. They did mention a few things. As I said, it appeared
5 that the filter fractured where all of the elements come in
6 towards the hook so they talked about changing the welding
7 pattern there. They talked about making the device is a bit --
8 the metal -- the metal legs and arms a bit thicker so that they
9 would be a bit stronger and they talked about strengthening the
10 hooks in order to reduce the ease that they could be displaced
11 from the cava wall.

01:34:38

01:34:58

12 Q. And was that basically the last communication you had with
13 anyone from Bard or NMT about the Recovery filter, at least
14 with respect to the issues we have been talking thus far today?

15 A. Yes.

01:35:20

16 Q. Now, did you ever -- let me ask this question: Did your
17 data from this study relative to complications during filter
18 placement, recurrent pulmonary embolism, death, filter
19 migration, et cetera, provide clinical data to support a
20 determination of substantial equivalence as a permanent filter?

01:35:42

21 MR. NORTH: Objection, Your Honor. 701 and '2. No
22 qualification.

23 THE COURT: Hold on just a minute.

24 Are you asking about an FDA determination, Mr. Lopez?

25 MR. LOPEZ: No, just whether or not his data --

01:36:08

United States District Court

MURRY R. ASCH, M.D - Cross

1 THE COURT: I think you need to rephrase it then
2 because it sounds like you did.

01:36:11

3 MR. LOPEZ: Okay.

4 BY MR. LOPEZ:

5 Q. Did Bard ask you to do any comparison between its device
6 and any other device?

01:36:15

7 A. No, they did not.

8 Q. This was a study just about the Recovery filter?

9 A. About the retrievability of the Recovery filter, yes.

10 Q. Was your study designed to establish any clinical data to
11 support its permanent use safely and effectively?

01:36:28

12 A. No, it was not.

13 Q. And was there any data that came out of your study that
14 would support its use as a safe and effective permanent filter?

15 A. No.

01:36:49

16 MR. LOPEZ: Those are the only questions I have, Your
17 Honor.

18 Thank you, Dr. Asch.

19 THE COURT: Cross-examination?

20 MR. NORTH: Yes, Your Honor.

01:36:57

21 **CROSS - EXAMINATION**

22 BY MR. NORTH:

23 Q. Good afternoon Dr. Asch.

24 A. Good afternoon.

25 Q. I believe you and I have met on one previous occasion when

01:37:28

United States District Court

MURRY R. ASCH, M.D - Cross

1 you were deposed in this case; correct?

01:37:32

2 A. That's correct.

3 Q. Let me be sure one thing is straight. Your work with Bard
4 in the development or testing -- or the clinical study of
5 filters had to do with the Recovery filter; correct?

01:37:44

6 A. That's correct.

7 Q. You never had any involvement with the design or
8 development of what is the G2 filter, did you?

9 A. That is correct.

10 Q. And you never conducted a clinical study about the G2
11 filter, did you?

01:37:55

12 A. That is correct.

13 Q. Are you aware that the plaintiff, Ms. Booker in this case,
14 was implanted with a G2 filter and not a Recovery filter?

15 A. I am not aware of that.

01:38:07

16 Q. How many IVC filters by any manufacturer have you placed?

17 (Court Reporter interrupted for clarification.)

18 THE COURT: Reask the question.

19 BY MR. NORTH:

20 Q. How many IVC filters have you placed in your clinical
21 practice over the years?

01:38:26

22 A. 400 or 500.

23 Q. And do you still place filters today?

24 A. Yes, I do.

25 Q. And you agree that IVC filters are an important device to

01:38:38

United States District Court

MURRY R. ASCH, M.D - Cross

1 have available for the care of your patients? 01:38:42

2 MR. LOPEZ: Your Honor, I'm going to object as beyond
3 the scope of my examination of this witness.

4 THE COURT: Your response, Mr. North?

5 MR. NORTH: I think I'll move along, Your Honor. 01:38:56

6 THE COURT: All right.

7 BY MR. NORTH:

8 Q. You did testify earlier, Dr. Asch, that you had reviewed a
9 number of the tests and studies performed on the Recovery
10 filter by NMT? 01:39:06

11 A. I was presented with the information. I didn't review it
12 as such.

13 Q. That was my question. You did not review each and every
14 study that NMT had conducted on that test, did you?

15 A. I did not. 01:39:19

16 Q. And you did not review the test reports for each test, did
17 you?

18 A. I did not.

19 Q. And did you see all of the migration studies performed by
20 NMT? 01:39:31

21 A. No.

22 Q. Did you see all of the fracture and fatigue tests
23 performed by NMT?

24 A. No.

25 Q. And did you see all of the simulated use tests? 01:39:35

United States District Court

MURRY R. ASCH, M.D - Cross

1 A. No.

01:39:39

2 Q. And the radio strength tests?

3 A. No.

4 Q. I believe you testified in response to one of Mr. Lopez's
5 questions that you were not concerned during your study with --
6 if that was a caudal migration in patient number nine; is that
7 correct?

01:39:46

8 A. No. I said I couldn't remember if there was a caudal
9 migration.

10 Q. Were you concerned as to whether there was a caudal
11 migration?

01:40:05

12 A. As I believe I said, I am concerned about any migration in
13 any direction when the filter should stay where I put it.

14 Q. Dr. Asch, you flew in to Phoenix today from eastern Canada
15 to give your testimony correct?

01:40:21

16 A. That's correct.

17 Q. And you have been paid a consulting fee or a fee by the
18 plaintiffs for appearing today; correct?

19 A. I'm not being paid a fee. I am being reimbursed for the
20 income that I lost by being here today.

01:40:32

21 Q. And what -- are you being compensated or reimbursed at an
22 hourly rate?

23 A. No. I'm being paid essentially at the daily rate to
24 replace the income that I would have earned had I stayed at
25 home.

01:40:47

United States District Court

MURRY R. ASCH, M.D - Cross

1 Q. And how much is that?

01:40:48

2 A. It's approximately \$5,000 a day.

3 Q. And you have been paid in the past by these same
4 plaintiff's attorneys which you've met with them, haven't?

5 A. Several years ago when we last met, yes.

01:40:58

6 Q. And when you gave a deposition in this case, they took
7 your deposition, the one I attended, you were paid an hourly
8 rate for attending that deposition; is that correct?

9 A. That's correct.

10 Q. And my understanding is at that time, you were paid at a
11 rate of \$600 an hour?

01:41:10

12 A. That's correct.

13 Q. And it is also my understanding or recollection that
14 several years ago you consulted with Mr. Lopez and some other
15 lawyers to prepare a declaration they submitted in some
16 litigation pending in Los Angeles; is that correct?

01:41:24

17 A. Yes, it is.

18 Q. And you were paid for that at the rate of \$600 an hour;
19 correct?

20 A. That's correct.

01:41:38

21 Q. You have not used a Bard filter since 2005; correct?

22 A. That's correct.

23 Q. Have you even spoken with a Bard employee since 2005?

24 A. Yes, I have.

25 Q. You have not published a paper on IVC filters since 2005,

01:41:57

United States District Court

MURRY R. ASCH, M.D - Cross

1 have you?

01:42:00

2 A. I believe that's correct.

3 Q. And it is true, isn't it, Dr. Asch, that after you left
4 Toronto and began working in the other hospital where you now
5 work that you -- after you quit working with Bard filters, you
6 started working with a company that is a competitor of Bard's
7 called Cook; correct?

01:42:17

8 MR. LOPEZ: Beyond the scope, Your Honor.

9 THE COURT: Overruled.

10 THE WITNESS: I had worked with Cook for many, many
11 years. I work alongside many companies. I have worked with
12 Cook since the beginning of my career.

01:42:31

13 BY MR. NORTH:

14 Q. And you have conducted studies for Cook regarding their
15 competitive filters; correct?

01:42:42

16 A. That's correct.

17 Q. You worked closely I believe with Mr. Carr, Rob Carr, from
18 Bard; correct?

19 A. Yes, that's correct.

20 Q. And based upon your previous testimony, it's my
21 understanding that you had no complaints with Mr. Carr and how
22 he interacted professionally with you?

01:43:06

23 A. That's correct.

24 Q. And I believe, as you told us before, he was helpful and
25 supportive of your work?

01:43:22

United States District Court

MURRY R. ASCH, M.D - Cross

1 A. Yes, that's correct.

01:43:24

2 Q. Now, your initial study that you published about involved
3 32 patients correct?

4 A. Yes.

5 Q. And then you went home to do -- to perform afterwards the
6 same procedure on another 26 patients for a total of 58;
7 correct?

01:43:36

8 A. Yes.

9 Q. And in those 58 patients, there was the one situation of a
10 migration that you discussed; correct?

01:43:52

11 A. Yes.

12 Q. And in those 58 patients, there was one instance of a
13 fracture that you reported; correct?

14 A. Yes.

15 Q. And both that migration and that fracture were
16 asymptomatic events; correct?

01:44:03

17 A. They were asymptomatic at the time they were discovered,
18 yes.

19 Q. In other words, the patients didn't have any symptoms or
20 pains or any outward manifestations of the complication;
21 correct?

01:44:16

22 A. That's correct.

23 Q. And after you completed the study with all 58 patients,
24 you went on to implant a number of Bard Recovery filters in the
25 course of your private practice for the next two or three

01:44:34

United States District Court

MURRY R. ASCH, M.D - Cross

1 years; correct?

01:44:37

2 MR. LOPEZ: I'm sorry. It's beyond the scope.

3 THE COURT: Overruled.

4 THE WITNESS: Yes, that's correct.

5 BY MR. NORTH:

01:44:41

6 Q. And I believe I've heard estimates that you think you may
7 have ultimately implanted as many as 200 filters?

8 A. Well, I think the question was asked was in my career so
9 my career started in 1989.

10 Q. I'm sorry. With regard to Recovery filters, approximately
11 how many do you think that you implanted?

01:45:00

12 A. After this study when I moved to my current hospital,
13 maybe 10 or 15.

14 Q. But you continued to implant them after you completed the
15 study?

01:45:20

16 A. Yes.

17 Q. And you continued to implant them after you had had that
18 one incident of fracture in your study; correct?

19 A. That's correct.

20 Q. And you continued to implant them after you had that one
21 incident of migration in your study?

01:45:38

22 A. Yes.

23 Q. And after you completed your study or after those two
24 events occurred, in none of the Recovery filters that you
25 implanted did you ever observe another fracture or another

01:45:51

United States District Court

MURRY R. ASCH, M.D - Cross

1 migration; is that correct?

01:45:54

2 MR. LOPEZ: Objection. Lacks foundation.

3 THE COURT: Overruled.

4 THE WITNESS: When I came to my current hospital, my
5 practice was to place filters on clinical need outside of a
6 study so these patients were not followed up. So the fact that
7 I didn't detect it doesn't mean it didn't occur. It just means
8 I didn't follow the patients to the same rigors as I did during
9 the study.

01:46:03

10 BY MR. NORTH:

01:46:21

11 Q. But regardless of whether your follow-up protocol changed,
12 the fact is, you have never saw another fracture or another
13 migration in the Recovery filters that you implanted. Is that
14 right?

15 MR. LOPEZ: Your Honor, lacks foundation.

01:46:33

16 THE COURT: Overruled.

17 THE WITNESS: I never saw an event but that doesn't
18 mean it didn't occur.

19 BY MR. NORTH:

20 Q. Let's talk a moment about your study. When you conducted
21 this study, and I believe in one of the exhibits that was
22 previously admitted by Mr. Lopez, when you wrote to the board
23 and Dr. Freeland (phonetic) seeking permission to do this
24 study, you reported them -- to them that you are satisfied.
25 You said: I am satisfied that this is a safe and efficacious

01:46:45

01:47:09

United States District Court

MURRY R. ASCH, M.D - Cross

1 device; is that correct?

01:47:14

2 A. Yes, it is.

3 Q. And you felt that a retrievable IVC filter could assist
4 patients and that's part of why you conducted this study?

5 A. That's correct.

01:47:22

6 Q. And the Canadian authorities approved your study and the
7 protocols for the study; correct?

8 A. Correct.

9 Q. And after you began this study, you reported several times
10 that the filter was easy to implant and easy to retrieve;
11 correct?

01:47:39

12 A. That's correct.

13 Q. Now, one event of course that you mentioned is patient
14 number nine which was the migration. Migration of filters had
15 been ordered in the literature before your study with the
16 Recovery filter; correct?

01:47:52

17 A. That's correct.

18 MR. NORTH: And if we could pull up Exhibit 557,
19 please.

20 BY MR. NORTH:

01:48:15

21 Q. I would ask you, Dr. Asch, to look at Exhibit 557 which is
22 an email chain, appears to be, but you see it appears to be
23 forwarding an email written by you to people regarding the
24 patient number nine. Do you see that?

25 A. Yes, I do.

01:48:30

United States District Court

MURRY R. ASCH, M.D - Cross

1 Q. And do you agree that that is forwarding an email
2 concerning you wrote of that patient?

01:48:35

3 A. I don't see the email in its completion here but, yes, I
4 believe that that is mine.

5 MR. NORTH: Your Honor, at this time we would offer
6 557.

01:48:50

7 MR. LOPEZ: No objection, Your Honor.

8 THE COURT: Admitted.

9 MR. NORTH: Can it be displayed to the jury, Your
10 Honor?

01:48:58

11 THE COURT: Yes.

12 (Exhibit Number 557 was admitted into evidence.)

13 BY MR. NORTH:

14 Q. If we could, let's look down probably the second or third
15 paragraph where it begins, "I believe."

01:49:13

16 A. Okay.

17 Q. You said: I believe that the filter migrated due to the
18 impact of the large thrombus -- and a thrombus is a clot;
19 correct?

20 A. Yes.

01:49:31

21 Q. -- and in doing so, likely saved this patient's life.

22 Is that what you were reporting?

23 A. Yes.

24 Q. And so it was your view at the time that while that filter
25 migrated, it probably saved the patient's life because of the

01:49:42

United States District Court

MURRY R. ASCH, M.D - Cross

1 size of that clot?

01:49:47

2 A. Yes but, again, the concern is that the filter could have
3 continued to migrate because now it was in a potentially
4 unstable position.

5 Q. And a couple of lines down you also indicated that you
6 believe that this is an isolated event, that filter migration
7 is a known complication of all currently approved devices.

01:49:59

8 Is that accurate?

9 A. That is what I said, yes.

10 Q. And then you also, as we discussed, mentioned patient 33
11 and that was the patient who had the fracture correct?

01:50:21

12 A. Correct.

13 Q. And I believe, as you mentioned, the study was stopped and
14 an investigation was conducted when that fracture occurred;
15 correct?

01:50:37

16 A. Correct.

17 Q. And Rob Carr, led that investigation, didn't he?

18 A. I believe so.

19 Q. And he published a lengthy report concerning that
20 investigation?

01:50:47

21 A. I don't recall. I assume he did. I don't recall.

22 Q. Did you and Mr. Carr in investigating that fracture,
23 conclude that it may have been the forces of the female
24 patient's labor and deliver that could have contributed to the
25 fracture?

01:51:12

United States District Court

MURRY R. ASCH, M.D - Cross

1 A. That was one of my hypothesis, yes. We were working on a
2 number of hypotheses, the patient factors and filter factors,
3 so that was one potential.

4 Q. And are you aware of the fact that based upon that
5 experience and that event in your clinical study, Bard took the
6 affirmative step to add instructions in the instructions for
7 use about how filters should be placed in pregnant patients?

8 A. Yes, I'm aware of that but those are standard instructions
9 for use for all filter manufacturers in pregnant women.

10 Q. Are you aware of the fact that Bard provided the FDA with
11 the data concerning both the migration and the fracture event
12 in your study?

13 MR. LOPEZ: Objection, Your Honor. Vague and
14 ambiguous.

15 THE COURT: Overruled.

16 THE WITNESS: I am not aware of what they provided to
17 the FDA.

18 BY MR. NORTH:

19 Q. Are you aware of the fact that in the instructions for
20 use, your study was described, the instructions for use given
21 out to every physician that received a Recovery filter, your
22 study was described and the event of migration and fracture
23 were mentioned in that description?

24 MR. LOPEZ: Objection, Your Honor. Best evidence.

25 THE COURT: Overruled.

United States District Court

MURRY R. ASCH, M.D - Cross

1 MR. LOPEZ: Hearsay. 01:52:33

2 THE COURT: Well, hold on. I can't hear the second
3 part of what you're saying.

4 MR. LOPEZ: I'm sorry, Your Honor. Best evidence and
5 hearsay. 01:52:40

6 THE COURT: Overruled on best evidence.

7 What's your response to the hearsay objection,
8 Mr. North?

9 MR. NORTH: I just asked him if he was aware of
10 whether that occurred. 01:52:51

11 THE COURT: Whether there was an out-of-court
12 communication?

13 MR. NORTH: Right.

14 THE COURT: I think that's hearsay. Sustained.

15 MR. NORTH: Okay. Thank you, Your Honor. 01:52:59

16 BY MR. NORTH:

17 Q. Do you recall whether there was any reference to those
18 events in the IFU?

19 A. I do not recall.

20 Q. Now, if we could look at Exhibit 558. Could you identify
21 for the members of the jury what 558 is? 01:53:13

22 A. That is a published manuscript that summarizes the
23 experience that I had with this new Recovery filter.

24 Q. And that is an article that you yourself published; is
25 that correct? 01:53:53

United States District Court

MURRY R. ASCH, M.D - Cross

1 A. Yes, that is.

01:53:55

2 Q. And in what journal was it published?

3 A. "The Journal of Radiology."

4 Q. And do you consider that a reliable publication?

5 A. Yes, I do.

01:54:08

6 Q. Would the study have been peer reviewed?

7 A. Yes, it would.

8 MR. NORTH: Your Honor, at this time I would tender
9 into evidence Exhibit 558.

10 MR. LOPEZ: I'm going to object to the hearsay
11 portion of this Your Honor.

01:54:19

12 THE COURT: What's your response on hearsay?

13 MR. NORTH: First of all, it's an admission by him.
14 These are statements that he authored. And then, secondly,
15 it's a learned treatise. He's already admitted under 803.18 I
16 believe it is meets the criteria.

01:54:29

17 THE COURT: Well, even if it's an admission by him,
18 he's not a party opponent so that doesn't get you around the
19 hearsay problem. 803.18. 803.18 does not allow an admission
20 of an exhibit.

01:55:03

21 MR. NORTH: Your Honor, I'm sorry, my understanding
22 was that the contents in it can be admitted to the jury but the
23 exhibit not sent back to the jury room.

24 THE COURT: Well, the exhibit does not come in. The
25 contents can be read at 803.18. I thought you were moving the

01:55:16

United States District Court

MURRY R. ASCH, M.D - Cross

1 exhibit into evidence.

01:55:20

2 MR. NORTH: I'm sorry. In some courts they move it
3 into evidence but don't send it back.

4 But may I display to it jury?

5 THE COURT: What's your response on 803.18?

01:55:30

6 MR. LOPEZ: I'll object, Your Honor.

7 THE COURT: On what basis?

8 MR. LOPEZ: It's hearsay. I don't know what he's
9 going to read from.

10 THE COURT: But he's using this to avoid the hearsay
11 problem. Do you disagree that it satisfies the learned
12 treatise exception?

01:55:38

13 MR. LOPEZ: Well, I don't think it's been
14 established.

15 THE COURT: I'm going to overrule that objection.
16 803.18 applies not only to learned treatises but periodicals.
17 This seems to me to be a periodical that is -- that satisfies
18 the requirements. So the contents can be read but the exhibit
19 itself won't go into evidence to the jury.

01:55:48

20 MR. NORTH: Right.

01:56:07

21 So may I display it, Your Honor, on the screen?

22 THE COURT: You can have him read it into evidence
23 but the exhibit doesn't come into evidence to be seen by the
24 jury under 803.18.

25 MR. NORTH: Okay.

01:56:19

United States District Court

MURRY R. ASCH, M.D - Cross

1 BY MR. NORTH:

01:56:23

2 Q. If we could turn, Dr. Asch, on page 843, do you see in the
3 middle column, there is a paragraph that begins with the word
4 "there." Could you read the first couple of sentences there?

5 A. There was a single occurrence 3 percent of asymptomatic
6 filter migration in this series of 32 patients. Migration is
7 typically defined in the literature as movement greater than
8 two centimeters. The reported incidence --

01:56:45

9 Q. Okay. That's all I needed you to.

10 And then if you could go over to the next page, 844,
11 and read the last paragraph beginning first few sentences that
12 begin, "In conclusion."

01:57:04

13 A. In conclusion, this preliminary special access use of the
14 Recovery Nitinol filter, a retrievable IVC filter, suggests
15 that the filter can easily be delivered via the femoral vein.

01:57:30

16 Q. Two more sentences down beginning with, "No substantial."
17 What do you see?

18 A. I said: No substantial complications were encountered in
19 this series.

20 Q. So even after acknowledging that a migration had occurred
21 in the initial part of your study, you published an article
22 that said no substantial complications were encountered in this
23 series; correct?

01:57:48

24 A. That is what I said, yes.

25 Q. Now if we could look at Exhibit 555. This is a second

01:58:22

United States District Court

MURRY R. ASCH, M.D - Cross

1 article or a letter to the editor in a medical journal that you 01:58:34
2 published; correct?

3 A. That's correct.

4 Q. And you had a couple of co-authors with this; is that
5 correct? 01:58:41

6 A. Yes, it is.

7 Q. And who were they?

8 A. One was a hematologist and one was an obstetrician
9 gynecologist.

10 Q. Did they work with you on your study? 01:58:53

11 A. No, they did not.

12 Q. And in what journal was this published in?

13 A. In the International Society on Thrombosis and
14 Haemostasis.

15 Q. And do you consider that to be a reliable medical journal? 01:59:11

16 A. Yes, I do.

17 MR. NORTH: Your Honor, at this time, I would seek
18 permission to have him read certain parts of the content
19 pursuant to the same exception.

20 MR. LOPEZ: Pursuant to the same exception, Your 01:59:23
21 Honor.

22 THE COURT: All right. You may.

23 MR. NORTH: Thank you.

24 BY MR. NORTH:

25 Q. Now, just to give the jury a little bit of the background, 01:59:28

United States District Court

MURRY R. ASCH, M.D - Cross

1 this second paper was after the entire study, all 58 patients,
2 were completed; correct?

01:59:30

3 A. I believe that's correct.

4 Q. And this was reporting on your experience with the
5 Recovery filter in all 58, including the migration and fracture
6 patient; correct?

01:59:43

7 A. No. This was -- no. This was really a summary of two
8 complications with filters in pregnant patients.

9 Q. But out of those 58 that you had studied; right?

10 A. Out of those, yes, 58.

02:00:03

11 Q. Now, turning to the last page on page 1097, read for us
12 the paragraph in the right-hand column about halfway down that
13 begins with, "There were no significant."

14 A. There were no significant complications in the use of the
15 IVC filter in our patients. The filter fracture that occurred
16 in the RNF patient was the only fracture that occurred in our
17 institution's series of 58 filters.

02:00:27

18 Q. And then go on to say what you said next, please.

19 A. This is a commonly accepted complication of IVC filters,
20 and has been previously reported with the Simon Nitinol filter
21 in up to 14 percent.

02:00:45

22 Q. So even in -- at the conclusion of the study, even in
23 reporting on the migration and fracture incident in your study,
24 you published an article in a reliable journal that said there
25 were no significant complications in the use of the IVC filter

02:01:05

United States District Court

MURRY R. ASCH, M.D - Cross

1 in our patients; correct?

02:01:10

2 A. That is what I said, yes.

3 MR. NORTH: Could we have Exhibit 567, please.

4 BY MR. NORTH:

5 Q. Doctor, you have seen the letter that is Exhibit 567
6 before; correct?

02:01:32

7 A. Yes.

8 Q. And it is a letter that you yourself wrote and signed?

9 A. Yes.

10 Q. And it's dated March 10 of 2003; correct?

02:01:42

11 A. Correct.

12 Q. And it regards the Recovery filter?

13 A. Yes.

14 Q. And who did you write this letter to?

15 A. I wrote this letter to Bard at their request so that they
16 could use it to obtain whatever approvals were required in
17 order to conduct the study that they had initially informed me
18 they were going to conduct, a long-term safety study on this as
19 a permanent filter.

02:01:57

20 Q. And when writing this letter, you knew that they -- it may
21 be presented to the United States Food and Drug Administration;
22 correct?

02:02:20

23 A. Yes.

24 MR. NORTH: Your Honor, at this time I would tender
25 for admission Exhibit 567.

02:02:31

United States District Court

MURRY R. ASCH, M.D - Cross

1 MR. LOPEZ: I object. It's hearsay, Your Honor. 02:02:35

2 THE COURT: Your response, Mr. North?

3 MR. NORTH: It is a letter that he wrote himself,
4 Your Honor.

5 THE COURT: It's an out-of-court declaration. Is 02:02:41
6 there a hearsay exception that applies?

7 BY MR. NORTH:

8 Q. Let me ask you this, Dr. Asch. At that time, were you
9 willing to represent to the FDA, knowing that it would be
10 presented to the FDA, that you strongly believed that the 02:02:58
11 development of the retrievable IVC filter was an important
12 advance?

13 A. Yes, it was an important advance that needed further
14 study.

15 Q. And you also were willing to tell the U.S. FDA that it was 02:03:12
16 a device that you needed for the treatment of patients in
17 Canada at that time correct?

18 A. A device like that, yes.

19 Q. And in fact, you continued during this same time period to
20 use that device for the treatment of your patients in Canada 02:03:30
21 correct?

22 A. Yes, I did.

23 Q. Thank you, sir. That's all I have.

24 THE COURT: Redirect?

25 MR. LOPEZ: Yes, Your Honor. 02:03:39

United States District Court

MURRY R. ASCH, M.D - Redirect

REDIRECT EXAMINATION

BY MR. LOPEZ:

Q. Okay. Dr. Asch, let's look at your study -- I'm sorry.
Let's look at Exhibit 558 and if we look over on the left-hand
side of the article where it says from the Department of
Medical Imaging. Do you see where I am?

A. Yes.

Q. And was this article supported in part with NMT medical
and C.R. Bard?

A. Yes, it was.

Q. And what does that mean?

A. It means that they paid me for my time, any time that I
devoted to working on the study, the proposal, gathering,
follow-up information, that they paid me an hourly rate for all
the work that I did.

Q. And this was -- actually, it was published in 2002. Does
that mean that the work was done sometime prior to that?

A. Yes. So, essentially, the work started after the initial
meeting in 1999.

Q. In fact, if you look, it says received November 14, 2001.
Do you see where I am?

A. Yes.

Q. And it was after that that you experienced the fracture
that caused Canadian Government and the Ethics Board to stop
the study?

United States District Court

MURRY R. ASCH, M.D - Redirect

1 A. I believe that's correct.

02:05:31

2 Q. Let's look at --

3 THE COURT: Is this the last -- which one is it?

4 MR. LOPEZ: It was the --

5 MR. NORTH: I think it was the next-to-the-last.

02:05:49

6 MR. LOPEZ: The 2005, next-to-the-last one, Your
7 Honor.

8 THE COURT: That's 555. The letter to the medical
9 journal.

10 MR. LOPEZ: Yes.

02:05:58

11 THE COURT: Yes. That's 555.

12 BY MR. LOPEZ:

13 Q. Can we put it 955 (sic). And let's look at the last page
14 of that article, please. And the bottom of the
15 second-to-the-last paragraph that talks about there was a
16 minimal degree of filter migration in the second case. So
17 there was a second migration in the study?

02:06:21

18 A. Yes.

19 Q. Which had no clinical consequences. And then it says:
20 Routine abdominal radiography is thus recommended for all
21 filter patients in order to identify filter fracture, slash,
22 migration. Do you see that?

02:06:36

23 A. Yes.

24 Q. Mr. North didn't read that, did he?

25 A. No.

02:06:50

United States District Court

MURRY R. ASCH, M.D - Redirect

1 Q. What does that mean, Doctor? Why would you recommend that 02:06:50
2 for the Recovery filter based on the history that you had with
3 the Recovery filter?

4 A. Well, again, we wanted to be sure that these patients are
5 monitored forward and complications of the filter are detected 02:07:06
6 while the patient is asymptomatic before they develop what
7 could be a lethal complication, so follow-up is important.
8 Follow-up is essential.

9 Q. There being no clinical consequences in your study, this
10 study had an average implantation I believe of 58 days; right? 02:07:27

11 A. Yes.

12 Q. And do we know what would have happened in that fractured
13 piece in patient 33 had she not been monitored and that piece
14 be allowed to flow freely in her vena cava?

15 A. Well, based on what we know since the -- those filters 02:07:44
16 have become used in standard clinical practice. The
17 expectation is that that filter or the filter fragment would
18 have migrated to the heart with a good likelihood of killing
19 the patient.

20 Q. This idea about asymptomatic, shouldn't doctors be 02:08:06
21 concerned that these patients could be experiencing a fracture
22 or a migration in their body if they are not being monitored
23 that an asymptomatic situation could actually be kind of a
24 silent killer?

25 A. Exactly. 02:08:24

United States District Court

MURRY R. ASCH, M.D - Redirect

1 Q. So the fact that something is asymptomatic should be of
2 concern to a company like Bard?

02:08:25

3 A. Yes, very much. It's a sign to look out for something
4 worse to happen.

5 Q. And do you think it would be prudent if Bard would include
6 in their instruction for use or when their salespeople call on
7 doctors to say, "By the way, we've got an issue with fractures
8 and migrations and tilting and perforations. We suggest that
9 you closely monitor these patients to make sure you find those
10 things before they become symptomatic"?

02:08:36

02:08:54

11 A. Yes. Bard should have said that.

12 Q. Now, sometime after you wrote this article in 2001 and
13 then you shared the experience of the fracture with other folks
14 in a letter to the editor where you recommend abdominal
15 radiography to deal with fractures and migrations, did you have
16 experiences in learning -- I'm sorry. Did you learn things
17 about the clinical experiences of your colleagues with the
18 Recovery filter?

02:09:25

19 A. Yes. Subsequent to that most recent article I did learn
20 that from talking to other colleagues and from reading more
21 recent publications that as the filter usage increased around
22 the world, there were more and more complications.

02:09:45

23 MR. NORTH: Your Honor, objection. I believe this is
24 hearsay.

25 THE COURT: Sustained.

02:10:03

United States District Court

MURRY R. ASCH, M.D - Redirect

1 BY MR. LOPEZ:

02:10:03

2 Q. Okay. Now, did there come a point after your study was
3 over and after Bard had said that they were going to look at
4 the design and make some design changes to this device that you
5 became concerned about your own patients that had Recovery
6 filters?

02:10:16

7 A. Yes, that's correct.

8 Q. And, again, these are patients that were not in the study.
9 These were patients when you were in a different hospital where
10 other doctors were referring them to you to put in a device and
11 then these patients would go back into their health care with
12 other physicians to be treated; true?

02:10:27

13 A. Yes.

14 Q. And when you became concerned about some of these patients
15 in whom you had placed a Recovery filter after this study, did
16 you contact Bard?

02:10:46

17 A. Yes, I did.

18 Q. And what did you ask Bard to do under those circumstances?

19 A. So I asked them to help me and facilitate me and my
20 institution in contacting all of the patients that I had placed
21 their filter into in order to follow them up and evaluate them
22 in the ways that I had suggested in my research project, do
23 abdominal radiographs, assess for the integrity and position
24 and try to ensure that we could get the filters out of these
25 patients to avoid the long-term complications, potential

02:11:01

02:11:20

United States District Court

MURRY R. ASCH, M.D - Redirect

1 long-term complications, because this filter had never been
2 tested for long-term stability.

3 Q. So were you concerned about some of your patients that had
4 now gone out of your care and gone back into the community or
5 located somewhere elsewhere, you might not see them again?

6 A. Yes, I was very concerned.

7 Q. And did you ask Bard to help you locate these patients so
8 that you can have them in to be evaluated in case they were
9 asymptomatic and had fractures and migrations in them as a
10 result of having a Recovery filter?

11 MR. NORTH: Objection, 402.

12 THE COURT: Overruled.

13 THE WITNESS: Yes, I did ask Bard for assistance in
14 locating my patients and following them up and they declined.

15 BY MR. LOPEZ:

16 Q. And they said no; right?

17 A. They said no.

18 Q. Now, let's talk about your compensation. When you were
19 doing this study for Bard and NMT, did they compensate you for
20 that?

21 A. Yes.

22 Q. Did they pay your expenses?

23 A. Yes.

24 Q. When you had meetings with them, did they pay for your
25 time?

United States District Court

MURRY R. ASCH, M.D - Redirect

1 A. Yes.

02:12:22

2 Q. And when you -- any time you spent in this study or doing
3 work for Bard, did you charge them an hourly rate just like
4 you're charging your hourly rate to be here today?

5 A. Yes, I did.

02:12:33

6 Q. And you wouldn't have expected anything other than for
7 Bard to be -- to pay you for your services correct?

8 A. I expect to be paid for any services as would anyone else
9 who is providing services.

10 Q. And they did that?

02:12:56

11 A. They did.

12 MR. LOPEZ: Those are the only questions I have, Your
13 Honor, at this time.

14 THE COURT: All right. Thank you. You can step
15 down.

02:13:16

16 MR. LOPEZ: Your Honor, I'm sorry. I apologize. I
17 have one follow-up question.

18 THE COURT: You may not step down. You can step back
19 up, please.

20 BY MR. LOPEZ:

02:14:20

21 Q. Dr. Asch, Mr. North asked you some questions about the
22 representation of your study in the 510(k) application. Do you
23 recall that?

24 A. Yes, I recall his question, yes.

25 Q. Did they ever consult you about doing that?

02:14:35

United States District Court

MURRY R. ASCH, M.D - Redirect

1 A. No.

02:14:37

2 Q. Did they have your permission to represent in an FDA
3 document that your study established safety and efficacy as a
4 long-term device, as a permanent device?

5 A. They did not request that and I would not have given that
6 permission. I wrote that letter at their request with the
7 assumption that they were going to use that as we discussed in
8 the very first meeting in 1999, to use that to create a
9 long-term safety study to see how that filter functioned as a
10 permanent device. That's why I wrote that letter, in order to
11 open the pathway for further study to occur.

02:14:53

02:15:13

12 Q. Now, Dr. Asch, if they represented, Bard represented to
13 our FDA that your study established the same safety and
14 effectiveness in the Recovery device as existed in the Simon
15 Nitinol device, would that be false and misleading?

02:15:38

16 A. Yes, it would.

17 MR. NORTH: Objection, Your Honor. 701, 702.
18 Regulatory expert.

19 THE COURT: Overruled.

20 BY MR. LOPEZ:

02:15:49

21 Q. I'm sorry. Your answer, Dr. Asch? Would that be false
22 and misleading?

23 A. That would be false and misleading, yes.

24 Q. Thank you, sir.

25 MR. LOPEZ: No further questions.

02:15:56

United States District Court

1 THE COURT: Okay. Thanks. 02:15:57

2 Doctor, you can step down.

3 (Witness excused.)

4 THE COURT: All right. Your next witness?

5 MR. LOPEZ: We're going to break -- I think we're 02:16:19
6 going to break into a video now, Your Honor, to kind of break
7 the ice here and show a video and give everybody a break from
8 our voices. We have a video deposition to show.

9 THE COURT: And that's what you want to do next?

10 MR. LOPEZ: Yes, sir. 02:16:32

11 THE COURT: Okay. Members of the jury, we're still
12 going to break at 2:30 but let me give you an instruction about
13 what you are about to see.

14 A deposition is sworn testimony of a witness taken
15 before trial. The witness is placed under oath to tell the 02:16:54
16 truth and lawyers for each party may ask questions. The
17 questions and answers are recorded by a court reporter or also
18 by a video recording. And when a person is unavailable to
19 testify at trial, the deposition of that person may be used at
20 the trial. 02:17:14

21 You're about to see a portion of a deposition of a
22 witness taken before the trial in this case. Insofar as
23 possible, you should consider this deposition testimony
24 presented to you by videotape in lieu of live testimony here in
25 court in the same way as if the witness presented it here 02:17:32

1 during the trial.

02:17:36

2 Please do not place any significance on the behavior
3 or tone of voice of any person reading the questions or answers
4 if that happens in the presentation of any deposition. And
5 this instruction will apply not only to the video we're about
6 to see but to a number of other presentations that will be made
7 to you during the trial of deposition testimony.

02:17:49

8 All right. You may -- which witness is this?

9 MR. LOPEZ: Dr. David Ciavarella.

10 THE COURT: All right. So you're going to play it?

02:18:12

11 MS. REED ZAIC: Yes, but I believe we have an agreed
12 summary of the background and credentials, Your Honor, in order
13 to save time on the tape.

14 THE COURT: Okay.

15 Are you getting a copy of the background?

02:18:54

16 MS. REED ZAIC: We are getting a copy of it.

17 THE COURT: All right. Counsel, let me make sure we
18 understand what you're doing.

19 MR. LOPEZ: Do you have a copy of the summary of his
20 background?

02:19:04

21 MR. NORTH: No. We've never seen it.

22 MR. LOPEZ: We can read the background information
23 after the video, Your Honor.

24 THE COURT: All right. That's fine.

25 MR. LOPEZ: Let me just say he's a former medical

02:19:12

1 director from Bard. He was there from 2004 through 2008 or '9 02:19:14
2 but he was there during the period.

3 MR. NORTH: My only correction is he's still employed
4 there today.

5 MR. LOPEZ: Oh. Okay. 02:19:28

6 THE COURT: You can begin playing the deposition.

7 This should be on your screen, ladies and gentlemen
8 and you should be able to hear it.

9 (Whereupon, videotaped deposition of Dr. David
10 Ciavarella was played for the jury.) 02:20:52

11 THE COURT: All right. Let's stop the deposition at
12 this point.

13 Latches, we'll take the afternoon break. We will
14 plan to resume at a quarter to three. We'll excuse you at this
15 time. 02:29:46

16 (Jury departs at 2:29.)

17 THE COURT: Counsel, let me remind you of what I said
18 in an order that came out last week. We're not having the
19 court reporters transcribe what is being played on the
20 deposition. So you should be sure to put in the record an 02:30:22
21 agreed-upon statement of what portions of the depositions were
22 read so that it's clear on appeal.

23 This portion we just watched showed a document which
24 the jury has seen and it was asked about. There's been no
25 discussion that I know of moving that into evidence. If so, 02:30:40

1 which exhibit number. What are your thoughts on that?

02:30:45

2 MR. LOPEZ: Actually, Your Honor, after your rulings,
3 I meant to actually offer to move all of the documents that
4 have been referenced in the depositions into evidence but we've
5 got to give you the exhibit numbers.

02:30:57

6 THE COURT: And you need to talk as well to see if
7 there's any objection about that. But, yeah, at that point,
8 the jury is going to need to understand that what was just
9 referred to as Exhibit 21 in this deposition is either
10 Exhibit 21 that's come into evidence or if it has a new number,
11 what the new number is.

02:31:14

12 So you might confer about how to do that with all the
13 depositions.

14 MR. LOPEZ: Okay.

15 THE COURT: I wanted to mention one thing. You
16 objected several times, Mr. Lopez, to beyond the scope during
17 the cross-examination. I overruled it. Every time I overruled
18 it, it was because the question was going to credibility, in my
19 view, which is not beyond the scope. That's always fair game
20 on cross-examination.

02:31:26

02:31:41

21 The last thing I wanted to mention is I have two
22 hearings at 4:30. Do we need time to talk through the issue
23 that came up earlier today about the Simon Nitinol information
24 or can we run right up to, say, 4:20 or 4:25 and break?

25 MR. LOPEZ: We can do that in the morning.

02:32:02

1 THE COURT: Well, do we need to do it at some point?
2 If we're going to do it this afternoon, we'll need to break
3 before 4:20 probably to address it. I'm just wondering, how
4 far we should go?

5 MR. LOPEZ: I'm ready to address it this afternoon,
6 Your Honor.

7 THE COURT: Have you all conferred about it?

8 MR. NORTH: I still don't know what documents he's
9 talking about.

10 THE COURT: You need to talk about it. So let's
11 rather than do it, let's take this after -- let's take it up at
12 8:30 tomorrow and we'll go to 4:20 with the jury today.

13 Okay. Thanks.

14 (Recess at 2:32; resumed at 2:47.)

15 (Jury enters at 2:47.)

16 (Court was called to order by the courtroom deputy.)

17 THE COURT: Thank you. Please be seated.

18 MR. LOPEZ: Your Honor, I'm wondering if I could read
19 off the exhibit that is going to be listed in the video and let
20 the jury write down the trial exhibit number. Would that be
21 possible?

22 THE COURT: Yes.

23 Is there any objection to its admission?

24 MS. HELM: Your Honor, we do have objection to the
25 admission of one exhibit.

1 MR. LOPEZ: I think we took it out. What number was
2 it?

3 MS. HELM: It's Ciavarella 28, Trial Exhibit 925.

4 MR. LOPEZ: It's part of the deposition that you
5 allowed to be played. I don't think we're showing -- if we
6 do --

7 THE COURT: Well, is this part of what was
8 designated, Ms. Helm?

9 MS. HELM: Your Honor, the foundation for the exhibit
10 was not designated.

11 THE COURT: Was there an objection made in the
12 transcript to the questions about the document?

13 MS. HELM: No, Your Honor.

14 THE COURT: All right. Then I'm going to allow you
15 to play it. What are the exhibit numbers?

16 MR. LOPEZ: Exhibit 21 is Trial Exhibit 1216.
17 Exhibit 28 is Trial Exhibit 925. Exhibit 33 is Trial Exhibit
18 991. Exhibit 35 is Trial Exhibit 927. Exhibit 39 is Trial
19 Exhibit 931. And Exhibit 40 is Trial Exhibit 1221.

20 THE COURT: 1221?

21 MR. LOPEZ: 1221.

22 THE COURT: And are you moving all of those into
23 evidence?

24 MR. LOPEZ: Yes, Your Honor.

25 THE COURT: Besides 925, is there any objection?

1 MS. HELM: No, Your Honor. 02:50:04

2 THE COURT: Okay. Then those other exhibits will be
3 admitted and you can play the transcript.

4 MR. LOPEZ: And the future transcripts, Your Honor,
5 we'll have something like this for the jury. 02:50:11

6 THE COURT: Okay.

7 (Exhibit Numbers 925, 927, 931, 1216, and 1221 were
8 admitted into evidence.)

9 (The deposition of Dr. Ciavarella continued to be
10 played.) 02:50:37

11 MR. LOPEZ: That concludes that deposition.

12 THE COURT: All right.

13 Your next witness?

14 MR. LOPEZ: At this time, plaintiff will call Alex
15 Tessmer. 03:20:23

16 MR. CONDO: Your Honor, may I be excused to bring him
17 in?

18 THE COURT: Sure.

19 If you want to stand up, ladies and gentlemen, while
20 the witness is coming in, feel free. 03:20:31

21 COURTROOM DEPUTY: Sir, if you'll please come
22 forward. Stand right here and raise your right hand, please.

23 (ALEX TESSEMER, a witness herein, was duly sworn or
24 affirmed.)

25 COURTROOM DEPUTY: Could you spell your last name for 03:21:07

us, please.

THE WITNESS: Tessmer. T-E-S-S-M-E-R.

COURTROOM DEPUTY: Great. Thank you.

Please have a seat.

DIRECT EXAMINATION

BY MR. LOPEZ:

Q. Good afternoon.

A. Good afternoon.

Q. You and I have never met before; is that true?

A. That's true.

Q. I know your deposition was taken but it wasn't me.

A. Got it.

Q. Okay. And are you still employed by Bard?

A. Yes, ma'am.

Q. And what is your current position there?

A. Ideation Marketing Manager.

Q. When you first started there, I think it was in January of 1997, was that right?

A. That is correct.

Q. And you went to the university -- you got a master's degree in business administration at the University of Phoenix; true?

A. Yes.

Q. And you got a degree in chemistry from ASU and at your deposition, you weren't sure whether it was '96 or '97. Which

ALEX TESSEMER - Direct

1 is it?

03:22:25

2 A. I think it was 1996 but I could have to look it up again.

3 Q. So in January of 1997 you went to work for Bard Peripheral
4 Vascular here I guess it was in Tempe; right?

5 A. Yes.

03:22:40

6 Q. And your position there was a microbiologist and you did
7 some testing?

8 A. Yes, that is correct.

9 Q. And then a year later you got an entry level engineering
10 position?

03:22:51

11 A. Yes.

12 Q. And then in 2005 you left Bard for a sales position at a
13 medical device company?

14 A. Yes.

15 Q. And then in January of 2012 you returned to Bard in a
16 marketing position?

03:23:02

17 A. That is correct.

18 Q. And that's what you do now --

19 A. Yes.

20 Q. -- marketing?

03:23:14

21 Okay. And have you had any involvement with IVC
22 filters since you returned?

23 A. Not with exception to the deposition.

24 Q. Okay. I think you may have told us earlier in your
25 deposition that you do pay attention to the sales figures?

03:23:29

United States District Court

ALEX TESSEMER - Direct

1 A. Oh, yes.

03:23:32

2 Q. Of IVC filters?

3 A. Well, across the board we look at all the sales figures,
4 so I wouldn't -- I would once in a while look at the IVC filter
5 sales, yes.

03:23:42

6 Q. And what is the first time you got involved with an IVC
7 filter that was being manufactured and sold by Bard?

8 A. I believe or what I can recollect from 15 years ago,
9 sometime in, like, 2002 I believe.

10 Q. And what occasioned you to get involved with the Recovery
11 filter at that time?

03:24:05

12 A. So my primary purpose when I was working with the Recovery
13 filter was manufacturing a jugular delivery system. So a
14 delivery system that they would approach from the jugular vein
15 in the neck and deploy the filter. And then I also helped the
16 team as needed with the different testing that they had, so
17 they pulled me into some aspects of the filter with regards to
18 testing.

03:24:21

19 Q. Now, was that testing done after the device was already on
20 the market?

03:24:38

21 A. I believe so.

22 Q. And so were there some issues with the performance of the
23 device when it was on the market? They asked you to come you
24 in and test?

25 A. What I can recollect is I was pulled in I think to a

03:24:50

ALEX TESSEMER - Direct

1 design review at one point where they wanted me -- the quality
2 person said, "Hey, we want to perform some characterization
3 testing on the filter," and so forth and they asked me -- they
4 needed my help to help with some of that testing and that's
5 what I did.

03:24:53

03:25:09

6 Q. Now, had you had any familiarity with the Recovery filter
7 before it went on the market?

8 A. I had some basic knowledge of the filter that was made out
9 of Nitinol and the design and so forth. And plus, because I
10 was developing the jugular delivery system, obviously, I had to
11 know the dimensions and so forth to put it within the system to
12 deliver it using a jugular approach. So I knew of the filter
13 when I was developing the jugular delivery system.

03:25:29

14 Q. You were there when NMT and Bard took over or acquired
15 NMT?

03:25:52

16 A. Yeah. I believe I was at Bard. It's hard for me to
17 recollect because it's 15 years ago, because I was working on
18 stent graphs and they they pulled me over to the filter team.
19 So I'm not sure if they had already started to bring it over
20 from NMT or the exact time.

03:26:10

21 Q. Okay. But what you do know is that whenever it came over
22 from NMT and before Bard marketed it, they didn't ask you to do
23 any testing then; right?

24 A. Well, they asked me to do some characterization testing.
25 I believe it was like post-market of when they launched the

03:26:24

ALEX TESSEMER - Direct

1 product.

03:26:29

2 Q. I meant -- it was probably my problem. I meant before it
3 was launched. They didn't ask you to do any testing before it
4 was launched; right?

5 A. Not that I recall.

03:26:41

6 Q. Do you recall what was called the filter franchise team?

7 A. The filter franchise team? Yes.

8 Q. And were you on that team?

9 A. I believe I was on the filter franchise team but to be
10 honest with you, you would have to put a document in front of
11 me for me to recollect exactly whether I was on that team. I
12 mean, I was on the filter team itself.

03:27:02

13 Q. And was Rob Carr the director of that team?

14 A. Yes, he was.

15 Q. And did you work for Rob Carr?

03:27:17

16 A. Yes. I worked for Rob Carr and I also worked for other --
17 at one point I worked for Rob Carr but then there was others
18 that took a leadership position and I worked for them who
19 worked for Rob Carr.

20 Q. And Rob Carr was also an engineer?

03:27:30

21 A. Yes, Rob Carr was an engineer.

22 Q. But when Rob Carr came over from NMT, did he have a
23 business role as opposed to an engineering role?

24 A. Well, he was a director of engineering so he was guiding
25 engineers I would say. In regards to a business role, I'm not

03:27:51

United States District Court

ALEX TESSEMER - Direct

1 sure if he was part of R&D so he wasn't part of the sales team 03:27:55
2 so I'm not sure if I'm clear on the question.

3 Q. Okay. It wasn't that important.

4 A. Okay.

5 Q. So when you were asked to get involved with the Recovery 03:28:07
6 filter and to look at some of the testing, the Recovery filter
7 was already on the market; right?

8 A. I believe so.

9 Q. And was the Recovery filter experiencing some performance
10 issues that they asked you to maybe look at the testing to see 03:28:21
11 whether or not some of the testing may have been the reason for
12 these performance issues?

13 A. I was asked specifically -- they wanted me to do some
14 characterization testing to show the differences for migration
15 for Recovery filters versus other permanent filters on the 03:28:41
16 market. So that's what I recall.

17 MR. LOPEZ: Excuse me one second.

18 THE WITNESS: Sure.

19 BY MR. LOPEZ:

20 Q. Do you remember your deposition being taken in this case 03:29:37
21 on the date June 12, 2013?

22 A. Yes, I do.

23 Q. You have it. From time to time I may refer you to your
24 deposition to maybe remind you of what you may have testified
25 to almost four years ago or actually five years ago. 03:29:51

United States District Court

ALEX TESSEMER - Direct

1 A. That's helpful, yes.

03:29:56

2 Q. Okay. So you have it there if you need it.

3 So when you were working on Recovery, Bard was in the
4 process of redesigning it, weren't they?

5 A. When I was there, we're always trying to re-innovate
6 devices so part of innovation is we're always trying to make
7 the best thing, whether it's an angioplasty balloon. So in
8 this case a filter. So, yes, I was aware that they were trying
9 to work on a subsequent design.

03:30:07

10 Q. Okay. Well the truth is they were working on a subsequent
11 design because they were concerned about its current design.
12 True?

03:30:25

13 A. That I do not -- that I was not made aware of. I mean,
14 our goal at Bard is to make safe and effective devices. So
15 they did not say, "Hey" -- I was never told as far as I'm aware
16 that, "Hey, we're designing a new filter because we don't have
17 one that works."

03:30:42

18 Q. I mean, my question is, they just decided one day that
19 let's just look at the Recovery filter and see if we can make
20 it better or is the truth that they were having problems,
21 patient safety problems, with the Recovery which is why they
22 were looking at it with respect to its design?

03:30:59

23 A. Yeah. And for that particular question, I would really
24 have to defer you to Rob Carr because he was making those type
25 of decisions. But, you know, based off my 20 years of

03:31:17

ALEX TESSEMER - Direct

1 experience in medical device history, we're always innovating
2 and coming up with new designs.

3 Q. Okay. Let's look at Trial Exhibit 1006, please.

4 Is it up there now, Mr. Tessmer. Do you see it?

5 A. Yes, I do.

6 Q. Do you see that this is a December 3, 2003 email?

7 A. Yes.

8 Q. And it's from Brian Hudson and you're included in this
9 email; correct?

10 A. That is correct.

11 Q. And the subject of this is a special design review for
12 Recovery-meeting minutes?

13 A. Yes, that's correct.

14 Q. So this was -- these were minutes of a meeting that you
15 attended in December of 2003?

16 A. Yeah, that is what this email says.

17 Q. Okay.

18 MR. LOPEZ: Your Honor, I would like to offer this
19 into evidence at this time.

20 MR. CONDO: No objection.

21 THE COURT: 1006 is admitted.

22 (Exhibit Number 1006 was admitted into evidence.)

23 BY MR. LOPEZ:

24 Q. Now, the Recovery filter was on the market most of 2002.

25 Do you remember that or is that testing your memory too much?

ALEX TESSEMER - Direct

1 A. It's difficult to recall that far back so I don't know the 03:32:48
2 exact timing or dates. But I know it was on the market at the
3 specified time right around there.

4 Q. Let me ask you, when was the big party that they had to
5 launch the device into the open marketplace, what they call a 03:33:00
6 full market release? When did that happen?

7 A. I do not know.

8 Q. If I were to tell you it was in January of 2004, that
9 wouldn't refresh your recollection?

10 A. That does not. I just don't recall. 03:33:14

11 Q. All right. So this is special design review for
12 Recovery-meeting minutes and if we go to the memorandum that is
13 the next page --

14 THE COURT: Do you want this displayed?

15 MR. LOPEZ: Oh. Yes, Your Honor. Please display it 03:33:27
16 to the jury.

17 BY MR. LOPEZ:

18 Q. And you'll see that your name is on this memorandum;
19 correct?

20 A. That is correct. 03:33:39

21 Q. Now, let's look at the first paragraph and let's highlight
22 that entire paragraph, please. This was a special design
23 review meeting that happened on December 5, 2003, to discuss
24 the Recovery filter and cone projects. The purpose of this
25 special review was to gain further understanding related to the 03:34:02

United States District Court

ALEX TESSEMER - Direct

1 design elements of these products in anticipation of the up and 03:34:06
2 coming full market release in January of 2004.

3 Does that help refresh your recollection that the big
4 launch of the Recovery filter into the marketplace with your
5 marketing and sales was in January of 2004? 03:34:20

6 A. Yes, that does. Thank you.

7 Q. And this is that month before. I assume plans were
8 already made with marketing and sales about how they were going
9 to come out with the Recovery filter onto the U.S. marketplace
10 sometime in January of 2004? 03:34:40

11 A. I would not -- I did not know about those plans because I
12 was a lowly level engineer but I'm sure they were making some
13 sort of plans.

14 Q. Okay. Let's look at the note. A special review will be
15 held prior to launch that will cover these topics. Do you see 03:35:01
16 that, sir?

17 A. Yes, I do.

18 Q. Let's look at what the topics are. The next paragraph
19 down. The elements that were reviewed during the meeting and
20 outlined in an earlier memorandum entitled "Special Design 03:35:14
21 Review for Recovery filter Objectives" dated December 4, 2003.
22 As defined in the previous memorandum, the level of review was
23 based upon the degree of risk obtained from the Design Failure
24 Modes and Effect Analysis, DFMEA, for the Recovery filter.

25 Did I read that correctly? 03:35:40

United States District Court

ALEX TESSEMER - Direct

1 A. That is correct.

03:35:41

2 Q. What is a DFMEA, do you know?

3 A. Design Failure Modes and Effects Analysis.

4 Q. And so they had had a report regarding the degree of risk
5 after having that report run. Is that what that says?

03:35:52

6 A. So the DFMEA is part of the overall design process to
7 understand the risks, the inherent risks, of what would could
8 go wrong with a medical device.

9 Q. So let's look at what happened at this meeting, the
10 following action items that resulted from the meeting. Let's
11 look at number one. There was -- it says related to the issue
12 of deployment force. Do you see that?

03:36:15

13 A. Yes.

14 Q. And that is an issue with the delivery device. Would that
15 be an issue with the delivery device?

03:36:32

16 A. Yes. So the deployment force, I would conclude from this
17 it would be from the delivery device.

18 Q. And then let's go down to number three, please, on this
19 page.

20 MR. LOPEZ: Can you highlight that, Greg, please.

03:36:45

21 Q. Related to the issue of migration, the review team would
22 like to see objective evidence of the following elements: A,
23 documentation that explains the establishment of the 50
24 millimeter mercury acceptance criteria for migration
25 resistance.

03:37:05

United States District Court

ALEX TESSEMER - Direct

1 Correct?

03:37:07

2 A. Correct.

3 Q. Why did they need that in December of 2003?

4 A. I do not recall why they were -- needed that because we
5 had -- that came from the 50 millimeters of mercury is, if I
6 recall correctly, came from NMT.

03:37:17

7 Q. So somebody was questioning the validity of that criteria?

8 A. It sounds like it from this document from what I'm reading
9 here.

10 Q. Could it be because by that time, there had already been
11 four clinically significant migrations of this device both
12 caudally and cranially before full market release?

03:37:36

13 A. I did not have -- I don't know about that but, you know,
14 for this particular document, what I'm reading in front of me,
15 it's just telling me that -- but I didn't know what you're
16 talking about now, I don't recall that.

03:37:57

17 Q. All right. We'll look at more documents here in a bit.

18 Please go to page two, B. And this is an action
19 item; right? And this is the one relating to migration.

20 Looking back at the page before to see objective evidence of
21 the following elements, B is a migration resistance study that
22 analyzes the performance of the Recovery filter in conjunction
23 with tilting and quality of legs/hooks.

03:38:25

24 Did I read that correctly?

25 A. Correct, yes.

03:38:43

United States District Court

ALEX TESSEMER - Direct

1 THE COURT: Not quite. You said quality instead of
2 quantity.

3 MR. LOPEZ: You're right. I did. Quantity of legs
4 and, slash, hooks.

5 THE WITNESS: Correct.

6 MR. LOPEZ: With that correction.

7 Thank you, Your Honor.

8 BY MR. LOPEZ:

9 Q. And they didn't tell you that at this meeting that they
10 needed to look at that because they already had reports before
11 full market release that there were issues with tilting and
12 they were concerned about the legs and the hooks of the
13 Recovery filter?

14 A. I don't recall that from this particular meeting that they
15 told me that.

16 Q. And they also wanted to do a migration resistance, number
17 C, Greg, study that compares the Recovery filter to competitive
18 products, for example Greenfield.

19 Did I read that correctly?

20 A. Correct.

21 Q. And they wanted to do a radio force study that compares
22 the Recovery filter to competitive products. Another example
23 would be Greenfield; correct?

24 A. Yes, that's correct.

25 Q. And F, migration resistance study that analyzes the

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ALEX TESSEMER - Direct

1 performance of the Recovery filter in conjunction with oval
2 and, slash, or, D-shaped IVC tracks, paren, and transitions
3 between these configurations, end paren.

03:39:50

4 Did I read that correctly?

5 A. Yes, you did.

03:40:05

6 Q. Are we talking about the environment of use there, the
7 distensibility and the dynamics of where this device is
8 being implanted?

9 A. I think for this particular thing with the D-shaped and
10 the oval, they were thinking about the various ways that
11 anatomy could present itself.

03:40:18

12 Q. In other words, they weren't talking about PVC pipe and
13 sausage casing any more as a standard to see how it would work
14 in a human being. They were actually talking about something
15 that more closely mimicked what was in the human body; true?

03:40:34

16 A. Well, for this particular, what they were talking about,
17 or what I recollect, is they wanted to create this D-shaped and
18 oval shaped tubing and then put sausage casing in it to
19 experiment with these filters.

20 Q. And then five related to the issue of hook dimensions, the
21 review team would like to see objective evidence in regards to
22 the design input history of the hook dimensions.

03:40:52

23 Did I read that correctly?

24 A. You read that correctly.

25 Q. So when you were at this meeting, no one said to you while

03:41:17

ALEX TESSEMER - Direct

1 you were there that we need to do all this because we have some 03:41:19
2 performance and safety issues that relate to the Recovery
3 filter before the full --

4 A. To be quite honest, it has been 15 years so I do not
5 recall. 03:41:31

6 Q. Okay. Now, eventually, they asked you to do some testing;
7 right?

8 A. That is correct.

9 Q. I would like you to look at what has previously been
10 marked as Trial Exhibit 2059. This is called a project status 03:42:12
11 report. Do you see that, sir?

12 A. Yes.

13 Q. And this involves, if you look at project milestones -- do
14 you see where I am there, project milestones?

15 A. Yes, I see this. 03:43:21

16 Q. And by the way, you're on this as a project member. Do
17 you see that where it says Alex Tessmer?

18 A. Yes, I do.

19 Q. So you would have gotten a copy of this, sir?

20 A. I think I should have gotten a copy of it if my name is on 03:43:30
21 it.

22 MR. LOPEZ: I would like to offer this into evidence
23 at this time, Your Honor.

24 MR. CONDO: No objection.

25 (Exhibit Number 2059 was admitted into evidence.) 03:43:39

United States District Court

ALEX TESSEMER - Direct

1 THE COURT: Admitted. 03:43:39

2 BY MR. LOPEZ:

3 Q. Okay. Before we go to project milestones, this also --

4 MR. LOPEZ: If you go to the box above that, Greg,
5 and to the left. 03:43:51

6 MS. REED ZAIC: Do you want this published,
7 Mr. Lopez?

8 MR. LOPEZ: I do. I'll get this right, Your Honor.
9 By tomorrow I'll --

10 THE COURT: You've used your nine warnings from me. 03:44:09

11 MR. LOPEZ: In other words, you've helped me for last
12 time.

13 BY MR. LOPEZ:

14 Q. So this -- again, this is -- the launch date is January
15 26, 2004. There's no question about that; right? We've seen 03:44:19
16 two documents that say that.

17 A. When was this document dated?

18 Q. If you go down to the bottom of the page, you'll see that
19 it's dated October 27, 2003.

20 A. Okay. Because what it's saying right here is original 03:44:42
21 date for the launch is the 26th and the latest best estimate is
22 the 26th.

23 So it could be that date could be changed again. I'm
24 not sure.

25 Q. Okay. 03:45:00

United States District Court

ALEX TESSEMER - Direct

1 A. But this is -- because it was dated in 2003, that's the
2 latest best estimate.

3 Q. All right. Now, let's go down to the -- just that whole
4 section all the way across the page from milestones through
5 items impacting target, slash, LBE dates.

6 Now, sir, they are already talking about redesigning
7 this device in October of 2003. Do you see that? Choose
8 redesign.

9 A. Yes.

10 Q. I mean, this thing is not launched yet and they are
11 talking about the fact that we ought to look at redesigning it.
12 Isn't that true?

13 A. Yeah, that's what it appears by this document.

14 Q. Let me tell you, when the sales force went out with the
15 Recovery filter, did they tell doctors or put in the brochure,
16 "Here's our Recovery filter; but what you should know is we're
17 redesigning it to deal with some of our design issues that
18 we've experienced before full market release."

19 Did that happen?

20 A. I'm not sure what the sales force was told, to be honest
21 with you.

22 Q. Okay. Can I have 2061, please.

23 Sir, looking at Exhibit 2061, this is an email from
24 you dated February 4, 2004; right?

25 A. That is correct.

United States District Court

ALEX TESSEMER - Direct

1 Q. I think the date on the last document for full market
2 release was January 24. So if 31 days in January, so this is
3 11 days later; right?

4 A. Yes.

5 Q. And they are talking about -- you are writing an email to
6 everyone who is on this email about updated filter migration
7 flow loop test fixture; true?

8 A. From what I read here, yes, that's true.

9 MR. LOPEZ: Your Honor, I would like to offer this
10 into evidence and have the jury -- have it be displayed to the
11 jury.

12 MR. CONDO: No objection.

13 THE COURT: Admitted. And you may display it.

14 (Exhibit Number 2061 was admitted into evidence.)

15 BY MR. LOPEZ:

16 Q. And, sir, if you look down at your message to everyone --
17 and by the way, before we do that, there are other people on
18 here at Bard. There's Brian Hudson, I think was he also in
19 engineering or R&D?

20 A. Yeah, Brian Hudson was a quality engineer.

21 Q. And then Robert Carr who we've heard about today.

22 A. He was my boss.

23 Q. And what you've done looks like ten days after this device
24 is in full market release, you're talking about doing a
25 critical test to determine the pressure of when inferior vena

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ALEX TESSEMER - Direct

1 cava filters migrate; true?

03:48:05

2 A. I'm talking about, yeah, fixture that is a critical test
3 to determine the pressure of when inferior vena cava filters
4 migrate.

5 Q. But even by then, no one told you they were having to look
6 at these tests because in 2003 they had experienced a migration
7 just like they had seen in the Asch report and that they
8 actually had three or four other migrations of this filter?

03:48:24

9 A. So I don't recall whether they talked about these
10 migrations or not. What I recall is, I was pulled into the
11 team to the characterize our filter in comparison with some of
12 the other filters.

03:48:41

13 Q. Okay. Let's look at those.

14 A. Sure.

15 Q. 2063, please. Again, this is from you -- by the way, why
16 are these from you? Why are these emails from you? Are you
17 conducting these tests?

03:48:57

18 A. So I'm the -- so, basically, I was assigned by Rob to
19 help. They needed to pull me in to perform some of these
20 testing. So, obviously, as I stated, before my main goal was
21 this jugular delivery system I was creating. So they put me in
22 to help out with testing and I had some technicians that worked
23 underneath me that actually performed the tests themselves.

03:49:25

24 But they pulled me to in take documentation from NMT to kind of
25 re-create some of the migration testing they did there and

03:49:48

ALEX TESSEMER - Direct

1 repeat it, you know, at our facility at Bard.

03:49:52

2 Q. Okay. And was there a concern about maybe the results
3 from the testing at NMT that maybe there were some false
4 readings or results that maybe weren't accurate?

5 A. At NMT, what I recall from documentation I've seen,
6 because of this trial, they passed everything with flying
7 colors.

03:50:12

8 Q. Okay. So let's look at the testing that was run and this
9 was reason on February 25, 2004. This is almost precisely a
10 month after full market release; correct, sir?

03:50:34

11 A. So this date right here, are you asking me about the email
12 that was on 2-25-2004?

13 Q. We can just go on to the next page. This is like a month
14 later; right? That's all I wanted to know, a month after full
15 market release?

03:50:51

16 A. This page. Yeah, this is probably a month after,
17 approximately, after the launch.

18 Q. Let's look -- so you ran these tests; right?

19 A. My technicians did the tests but I reported on them.

20 Q. Tell us about the tests. What was the purpose of this
21 particular test?

03:51:07

22 A. I need to actually see the document because -- is this the
23 comparison test where we did the one between other filters?

24 Q. Let's go to the next page, please. Maybe this will help
25 refresh your recollection. Does that help or do you need to

03:51:33

United States District Court

ALEX TESSEMER - Direct

1 see more pages of it?

03:51:36

2 MR. LOPEZ: Keep going there, Greg. If you zoom
3 in -- go to the next page, the next page. Next page. There
4 you go.

5 BY MR. LOPEZ:

03:51:51

6 Q. Does that help refresh your recollection that this was a
7 study to see how you stacked up against your competitors when
8 it came to migration resistance?

9 A. It appears so. I don't know if all the results are on
10 these pages, though.

03:52:04

11 Q. Well, let's find out. Let's go back to the first page.
12 Actually, the second page of the exhibit where we have some of
13 the results. Before we get into that, we'll talk about it a
14 little bit.

15 MR. LOPEZ: I would like to offer 2063 into evidence,
16 Your Honor.

03:52:22

17 MR. CONDO: No objection.

18 THE COURT: Admitted.

19 (Exhibit Number 2063 was admitted into evidence.)

20 MR. LOPEZ: And I would like to have it published to
21 the jury.

03:52:32

22 THE COURT: You may.

23 BY MR. LOPEZ:

24 Q. Okay. Let's look at --

25 MR. LOPEZ: If you can blow it up just so we can

03:52:38

United States District Court

ALEX TESSEMER - Direct

1 actually see it on the screen, just that top half. There we
2 go.

03:52:40

3 Q. Now, RF is the sample. What does RF stand for in this
4 test?

5 A. I would assume that would stand for Recovery filter.

03:52:52

6 Q. Okay. And there were -- if you go all the way down to the
7 bottom of the page, you don't have to move off the screen.

8 Well, you do. You don't have a hard copy. If you can move it
9 down to the bottom of the screen, you'll see that there are,

10 what, 20 samples of Recovery filter that were run?

03:53:07

11 A. That appears to be correct, yes.

12 Q. And then if we can go back to the top -- by the way, was
13 there anything wrong with your equipment that day?

14 A. I would have to see the whole full report.

15 Q. Well, if there was a problem, you would have put that in a
16 report somewhere; right?

03:53:26

17 A. Yeah. I would put something in the report most likely,
18 yes.

19 Q. And these are the results of -- let's look at the first
20 ten samples of the Recovery filter and I note there are run
21 one, two and three. Does that mean the same device was
22 challenged three different times?

03:53:42

23 A. That is correct.

24 Q. And if you look at -- by the way, was the company still
25 using 50 millimeters of mercury as the safety threshold for

03:53:58

ALEX TESSEMER - Direct

1 migration at this time?

03:54:03

2 A. So depending on what testing we were doing, we would have
3 acceptance criteria or not. For our design verification and
4 validation qualification that we did, all our filters tested
5 above that acceptance criteria, 50 millimeters of mercury, and
6 we did what is called characterization testing.

03:54:19

7 So from this document that I'm seeing right here, I'm
8 not sure which exact characterization testing was done, whether
9 this was filters that were repeatedly used or, you know, bent
10 up or out of shape but so -- does that answer your question?

03:54:39

11 Q. Well, kind of. But you threw something in that's not in
12 this exhibit. You're talking about whether or not they were
13 bad filters, whether or not they were used again. If that
14 happens, wouldn't an engineer who was paying close attention to
15 what he was doing actually record that somewhere?

03:54:55

16 A. Yeah. We record that in the engineering report.

17 Q. Okay. Was there any such report of that happening in this
18 test, that there were problems with the filters?

19 A. Well, you would have to show me the entire engineering
20 document because all you're showing me is a data table, so I
21 have no idea what report this is coming from or what I'm
22 exactly testing, if that makes sense.

03:55:11

23 Q. Let's just look at the results right now of this testing.

24 A. Sure.

25 Q. In the first 10 filters that were challenged a total of 30

03:55:23

ALEX TESSEMER - Direct

1 times, what was the average migration resistance of those 10
2 filters?

03:55:31

3 MR. LOPEZ: Greg, can you go over to the right-hand
4 side?

5 THE WITNESS: The average, I see it right here, 45.2
6 millimeters of mercury.

03:55:43

7 BY MR. LOPEZ:

8 Q. That is below 50, isn't it?

9 A. That is below 50.

10 Q. It's below 80 for sure.

03:55:53

11 A. It is below 80.

12 Q. And you actually record -- by the way, before I go any
13 further, what's 37 plus or minus two?

14 A. That is the temperature at which the test was tested.

15 Q. Is that -- what's the Fahrenheit?

03:56:07

16 A. That would be approximately 98.6 degrees Fahrenheit.

17 Q. And the size of the diameter of the tubing was 28
18 millimeters?

19 A. That is correct, 28 millimeters.

20 Q. The indicated diameter for Recovery filters?

03:56:22

21 A. That is correct, 28 millimeters.

22 Q. And if you look at some of these results, a lot of them
23 are under 50; right? There's a -- there's some forties,
24 there's some 32s, 30s, 40s. I mean, most of these are under
25 50?

03:56:44

United States District Court

ALEX TESSEMER - Direct

1 A. Yes, that's correct.

03:56:48

2 Q. And then if you go down -- then we took another ten
3 filters, right, in the next set down on this page.

4 Did you share this with everybody by the way, the
5 results of these tests?

03:57:11

6 A. Yeah. I mean, the tests would be shared with -- to Rob
7 Carr and the other people, yeah.

8 Q. Did you have a meeting to discuss these findings?

9 A. I can't recollect if we had a meeting specifically about
10 this document from 15 years ago but we could have.

03:57:26

11 Q. And this was done at Bard, right, these tests?

12 A. I believe this was done at Bard.

13 Q. Okay. If we look at the next group, we see that while the
14 average was 51.5 for this next ten samples of Recovery filter,
15 we still see a number of runs, whether it be the first run or
16 the third run, that are under 50, in the forties and thirties,
17 don't we?

03:57:59

18 A. Yes, we do.

19 Q. You just had a couple high ones in there that brought the
20 average over 51.5; right?

03:58:18

21 A. Yes.

22 Q. But you happened to get one of the filters that had the
23 43.4, another a device that was being sold that was below your
24 minimum 50 millimeters of mercury threshold; true?

25 A. Or if these were the manufactured filters from the line,

03:58:38

ALEX TESSEMER - Direct

1 then, yes, but I'm not -- again, because you haven't shown me
2 the whole report, was this an experiment we ran on different
3 types of filters? I mean, do you know what I'm saying? We ran
4 various experiments. So were we testing parameters, the
5 osinite, martensite, (phonetic) you know, doing some things.
6 So I'm not clear what this actually is.

7 Q. Okay. Let me remind you, the first page of this, the
8 subject is filter migration test results; right?

9 A. Yeah. That's exactly what it says but I don't know what
10 these samples are from this document.

11 Q. You don't think they are from Bard's filters? You didn't
12 make these yourself, did you, and bring them from home?

13 A. No. No. But what I'm saying is, I don't know what these
14 were. Were these a ranging study that were performing with
15 different parameters and so forth. So that is what I'm trying
16 to communicate.

17 Q. Sounds to me like they were migration resistance tests.

18 A. Well, it was definitely a migration resistance test. I'm
19 just wondering, did these actually come from the manufacturing
20 line or was this some type of side experiment we were running?
21 From this document I don't know.

22 Q. You know, I'm going to let Mr. Condo worry about that
23 part, okay?

24 A. Okay.

25 Q. Let's go to the second page because this is what was given

ALEX TESSEMER - Direct

1 to us about these tests; all right? So let's look at the
2 second page. What does SF stand for?

3 A. I would imagine that would mean Simon Nitinol filter.

4 Q. Okay. and the Simon Nitinol filter was another device that
5 was being sold by Bard? 04:00:25

6 A. That is correct.

7 Q. And you wanted to see how the migration resistance, at
8 least on the bench with the new protocol you had for this
9 testing, stacked up against the Simon Nitinol filter; correct?

10 A. Yes, that is correct. 04:00:40

11 Q. Let's see how it stacked up against the Simon Nitinol
12 filter. We did -- you did ten runs -- I mean, ten filters,
13 three runs. Do you see that, sir?

14 A. Yes.

15 Q. And the average was 76.3; correct? 04:00:53

16 A. That is correct.

17 Q. Almost 30 points higher than the first run of the Recovery
18 filter; right?

19 A. That is correct.

20 Q. And if we go down to the next five samples of the Simon
21 Nitinol filter, the migration resistance in 40 degrees -- I'm
22 sorry, I should have pointed out in the last one of the reason
23 these are separated is because one is at normal body
24 temperature and the one below is if you have a higher body
25 temperature; true? 04:01:26

United States District Court

ALEX TESSEMER - Direct

1 A. That is true.

04:01:27

2 Q. Thank you. And the average in a higher body temperature
3 for the Simon Nitinol filter was 89.1?

4 A. That is correct.

5 Q. All right. Now let's go to the next page. Actually,
6 there's -- there were ten in that group. It's just that it
7 spills over to the next page. Let me just show him that.

04:01:36

8 Do you see, that sir?

9 A. Yes, I do. Thank you.

10 Q. Now, let's go to the next page. And what does VT stand
11 for?

04:01:53

12 A. That I'm not sure. I think there was one maybe called the
13 VenaTech but I would have to look back at the report.

14 Q. All right. Let me ask you -- you're not sure, is that
15 what you just said?

04:02:12

16 A. Yeah, because I can't remember the acronym VT. There was
17 a Tulip and there was another type of device so I'm trying to
18 remember which one this was.

19 Q. Let me ask you this: You were presented with this exhibit
20 at your deposition. Do you remember this?

04:02:26

21 A. I did not see it in this form that I recall. Oh, at my
22 deposition?

23 Q. Yes, at your deposition.

24 A. Okay.

25 Q. And you knew that you were going to be asked about this

04:02:37

United States District Court

ALEX TESSEMER - Direct

1 document in this trial in front of this jury; true?

04:02:38

2 MR. CONDO: Objection, Your Honor. Argumentative.

3 THE COURT: Overruled.

4 THE WITNESS: I had my deposition, yeah, but I did
5 not have a chance to go through my entire deposition prior to
6 this.

04:02:51

7 BY MR. LOPEZ:

8 Q. So, in other words, to be prepared to come here in front
9 of this jury to talk about important issues that relate to the
10 testing of the Recovery filter, you didn't go back and look at
11 this test to see whether or not you could tell us what VT stand
12 for?

04:03:02

13 A. I don't know what it stands for.

14 Q. It might stand for VenaTech. Let's assume it does for the
15 moment.

04:03:17

16 A. Okay.

17 Q. Let's look at the result of the migration resistance
18 testing for the VenaTech, a competitor of the Recovery filter;
19 correct?

20 A. That is correct.

04:03:27

21 Q. And what was the average score for migration resistance
22 testing of the VenaTech?

23 A. 84.5 millimeters of mercury.

24 Q. And by the way, this wasn't VenaTech's company giving you
25 their test results. This was you running tests on the

04:03:40

United States District Court

ALEX TESSEMER - Direct

1 VenaTech; right?

04:03:44

2 A. That is correct.

3 Q. Next page, please. GS1, can you tell us what that stands
4 for?

5 A. Maybe the Greenfield Stainless.

04:04:05

6 Q. Okay. Let's just assume it's the Greenfield for the
7 moment. Another competitor device of the Recovery and the
8 Simon Nitinol filter. True?

9 A. True.

10 Q. In fact, the Greenfield was a predicate device that Bard
11 used to get 510(k) clearance of its Recovery, isn't it?

04:04:18

12 A. I do not recall.

13 Q. Okay. But let's assuming it was. Let's assume that the
14 Greenfield -- that the Recovery filter had to be substantially
15 equivalent from a migration resistance standpoint to the
16 Greenfield filter. Does this test show that it is not
17 substantially equivalent at least from this test to the
18 Recovery filter?

04:04:36

19 A. So from this test from a migration resistance, it appears
20 that it's a higher average number than the Recovery filter, but
21 I'm not sure how it statistically stacks up with the
22 statistical significance. One thing with this test is you
23 notice it has a high range. You can see 59 to 112, so it could
24 be statistically equivalent. I'm not sure.

04:04:54

25 Q. Are you saying the results of this test have no meaning at

04:05:16

United States District Court

ALEX TESSEMER - Direct

1 all that we should just ignore them?

04:05:20

2 A. Oh, No. I'm not saying that at all. I'm just saying I
3 don't know what the statistical significance is; but the
4 average in this test, as we talked about, is greater than the
5 Recovery filter, correct.

04:05:33

6 Q. Let's look at the next page, please, and GT, do you think
7 that means Günther Tulip?

8 A. Yes, I believe it doe s.

9 Q. It's a retrievable device, right, sold by Cook?

10 A. That is correct, yeah.

04:05:47

11 Q. And a competitor of the Recovery filter?

12 A. Correct, a competitor.

13 Q. And what are the results of the tests that you ran on the
14 Günther Tulip in February in 2004?

15 A. It shows here that it was 110 millimeters of mercury.

04:06:04

16 Q. And then 89.6 was the average; right?

17 A. That is correct.

18 Q. Next page. TP. What is TP?

19 A. Oh, that's a TRAPEASE.

20 Q. So TRAPEASE still on the market?

04:06:25

21 A. I believe so.

22 Q. And it looks like the Recovery is pretty close to the trap
23 piece as far as migration resistance; right?

24 A. That is correct.

25 Q. Is the TRAPEASE a retrievable device?

04:06:42

United States District Court

ALEX TESSEMER - Direct

1 A. The TRAPEASE is not a retrievable device. It's a
2 permanent filter.

3 Q. And is it indicated for a vena cava size as large as 28
4 millimeters? Do you know?

5 A. I do not know.

6 Q. And then the next page, T, what does that stand for?

7 A. I do not recollect.

8 Q. Well, let's find out from another means. This is another
9 competitor; right?

10 A. I would think so.

11 Q. And then the average migration resistance for this test
12 that you ran on this competitive product was 122 average
13 millimeters of mercury; correct?

14 A. That is correct.

15 Q. And then the next page, O, I'm going to take a wild guess
16 and say that's OptEase?

17 A. I believe you would be correct.

18 Q. And that is a retrievable filter; true?

19 A. That is correct.

20 Q. And the average migration resistance of the OptEase was
21 136.6; correct?

22 A. That is correct.

23 Q. When you share these results with Rob Carr and others, do
24 you recall whether any of them expressed some concern about
25 these comparative results?

United States District Court

ALEX TESSEMER - Direct

1 A. I don't recall because it was 15 years ago. But certainly 04:08:07
2 there would be discussion about these results.

3 Q. I know there's other tests we're going to go through and
4 there's issues in this case; but just based on that bench
5 testing alone, would it be appropriate for Bard to tell doctors 04:08:23
6 that their device was performing just like every other device
7 on the market from the standpoint of migration, no better, no
8 worse?

9 MR. CONDO: Objection, Your Honor. There's no
10 foundation. He doesn't know what these tests were. 04:08:41

11 THE COURT: Sustained on foundation. I think you
12 need to lay foundation about marketing statements.

13 MR. LOPEZ: I'll move on, Your Honor.

14 Can we look at Exhibit 1369?

15 BY MR. LOPEZ: 04:09:02

16 Q. Before we do that, the results of those tests that we just
17 saw were passed on to Mr. Chanduszeko, Mr. Carr, and Mr. Hudson;
18 correct?

19 A. That was at the previous email I sent you showed me.

20 Q. If you need to be remind -- refreshed, you can look at 04:09:17
21 page 148, page 20 of your deposition.

22 A. What line?

23 Q. 148, line 20 through 22. I'm having you do that because I
24 want to make sure that we know who you sent the test to.

25 A. Yes. So I'm not sure if it's -- this is referring to that 04:09:59

United States District Court

ALEX TESSEMER - Direct

1 document there but I would certainly, you know, typically send
2 these results to Brian Hudson and Rob Carr.

04:10:04

3 Q. Okay. And how about Mr. Chanduszko?

4 A. He would probably be included as well I would think but
5 definitely Rob Carr, my superior, and then Brian Hudson. I'm
6 not sure if Andre saw all of these results or not.

04:10:19

7 Q. Well, after the results of this test, did you or did
8 anyone say, "Well, we ought to look into this more thoroughly
9 and decide whether or not we ought to reconsider having this
10 filter on the market until we can figure out whether or not
11 these tests are valid"? Did anyone say that?

04:10:40

12 A. So, you know, I don't recall the exact specifics of what
13 this testing was and what exactly those were, those filters,
14 but we would certainly discuss any of these items and, you
15 know, we always want to have a safe and effective device. But,
16 again, I was a testing person, so a lot of those conversations
17 I would default to Rob Carr.

04:10:59

18 Q. Let me ask you this question: Can you think of anything
19 as you sit here today, based on your memory or based on
20 anything you may have reviewed before you came here to testify,
21 that you think would invalidate the results of the test results
22 we just went through?

04:11:18

23 A. That could invalidate these results?

24 Q. Right.

25 A. Well, if these filters were not -- if this was an

04:11:32

ALEX TESSEMER - Direct

1 experiment that we were testing out at different -- you know, a 04:11:35
2 whole different filter design, then that would invalidate all
3 of these because these weren't the manufactured filters that we
4 put out there, if that makes sense.

5 Q. Do you know today whether or not that's the case, that 04:11:47
6 they were not, you know, manufactured?

7 A. Yes. So for this particular set of samples, you know,
8 because I don't have the engineering report right here to look
9 at, I don't know what those came from. That's all I'm saying.

10 I'm just trying to be honest about that. I don't know -- 04:12:04
11 because we performed experiments, right. And sometimes we
12 would tweak different parameters to find out how the filter
13 would behave.

14 I don't know if this was an experiment to try out
15 different things. Was this an actual filter that we sent to 04:12:17
16 the market is what I'm saying. You know, that is questionable
17 because I don't --

18 Q. Is Mr. Condo going to surprise me with a document that
19 explains all that?

20 MR. CONDO: Objection. 04:12:34

21 THE COURT: Sustained.

22 MR. NORTH: Move to strike the question, please.

23 THE COURT: There's no answer. Questions are not
24 evidence.

25 MR. CONDO: Thank you, Your Honor. 04:12:41

United States District Court

ALEX TESSEMER - Direct

1 BY MR. LOPEZ:

04:12:43

2 Q. If you're trying to see how you stack up against
3 competitors, you don't think you would, like, try to find the
4 best possible samples you could possibly find to run those
5 tests?

04:12:54

6 A. What I'm saying is I don't know if this was a ranging
7 study that wasn't the final design of the product. That's all
8 I'm saying. That's why I'm -- it would be great to see the
9 report in context to see what these filters were exactly, how
10 they were manufactured and were they the ones that we actually
11 sent out into market.

04:13:10

12 Q. Well, how about the competitive products? Aren't those
13 products that were actually being sold by those companies?

14 A. That is correct.

15 Q. And you went out and actually got real devices that were
16 being sold by the company; right?

04:13:25

17 A. Yeah. We would go out and get competitive samples because
18 we wanted to test and see how we compared.

19 Q. And don't you think that the appropriate protocol for a
20 test like that would be for you to use a similar sampling from
21 the Recovery filter? In other words, the filters that you
22 would actually be selling and maybe even boxed?

04:13:41

23 A. So, again, I just don't know where these samples came
24 from.

25 Q. I understand but don't you think from the standpoint --

04:13:55

United States District Court

ALEX TESSEMER - Direct

1 just as an engineer. I know you probably don't remember doing
2 these steps. But you went out and got competitive samples --

3 A. Correct.

4 Q. -- of devices that were really being sold.

5 In order to get a fair comparison, don't you think
6 that the Recovery samples should have also been devices that
7 were really being sold at the time?

8 MR. CONDO: Again, objection. There's no foundation.
9 He's testified several times.

10 THE COURT: Overruled.

11 THE WITNESS: So I think there's other studies, too,
12 that we did a comparison study that was different from this and
13 that is why I'm having trouble here.

14 BY MR. LOPEZ:

15 Q. All right. I'm just going to move on. Do we have 1369 up
16 there, going?

17 MR. WOODY: Yes.

18 THE COURT: Thank you.

19 BY MR. LOPEZ:

20 Q. 1369 is now we're in March 24, 2004. Do you see that?

21 A. Yes, I do.

22 Q. And that -- this is another memo from you?

23 A. That's correct.

24 Q. To Rob Carr, Brian Hudson, Charlie Benware, and Ed
25 Fitzpatrick; correct?

United States District Court

ALEX TESSEMER - Direct

1 A. That's correct.

04:15:13

2 Q. And these relate to Starguide filter migration test
3 results. Do you see that, sir?

4 A. Yes, I do.

5 Q. And is this a document you were able to review before you
6 showed up today?

04:15:20

7 A. Yes, I was is.

8 Q. Can we look at this document, please. If we can look at
9 the -- first of all, what is Starguide?

10 A. So Starguide was a manufacturer of the Nitinol wire.

04:15:38

11 Q. And what was the purpose of doing the test on the
12 Starguide material?

13 A. So what I recollect is Glens Falls, we had a wire we were
14 already using to make the filter and so they were pulling in
15 another manufacturer for either cost-savings reasons or to --
16 maybe they liked this Nitinol wire better for some reason. For
17 whatever reason, they were trying to bring in this other
18 manufacturer so they wanted to test to see how this Starguide
19 wire would perform.

04:16:02

20 MR. LOPEZ: Your Honor, I would like to move 1369
21 into evidence and have it shown to the jury.

04:16:22

22 MR. CONDO: No objection.

23 THE COURT: Admitted.

24 And you may display it.

25 (Exhibit Number 1369 was admitted into evidence.)

04:16:30

United States District Court

ALEX TESSEMER - Direct

1 BY MR. LOPEZ:

04:16:31

2 Q. Okay. So let's go down to the body of this one-page
3 document. And is this another test you were asked to run?

4 A. That is correct.

5 Q. Whatever happened -- are there any memos that you've seen
6 or any further discussions or meeting minutes that you've seen
7 since the February 2004 migration resistance testing versus
8 competitors and the Simon Nitinol filter? Do those exist?

04:16:50

9 A. After this document?

10 Q. No. Before.

04:17:08

11 A. There should have been some emails or different
12 communication, yeah, or characterization testing performed.

13 Q. So this deals with another set of migration resistance
14 tests?

15 A. That is correct.

04:17:29

16 Q. And you tested a total of 40 filters?

17 A. Yes.

18 Q. Each filter was tested three times for a total of 120
19 runs?

20 A. Yes, that is correct.

04:17:42

21 Q. And then if you go down -- so what you did here is you
22 compared -- is it a comparison between the wire you got at
23 Starguide versus wire you got at somewhere else?

24 A. That is correct.

25 Q. And then what you found out was that if you look where it

04:18:00

United States District Court

ALEX TESSEMER - Direct

1 says: You will quickly notice that there were values below 50
2 millimeters of mercury acceptance criteria for all the three
3 Starguide manufactured lots; correct?

04:18:06

4 A. Yes, that is correct.

5 Q. Since this was the case, we tested filters manufactured
6 using the current supplier wire to determine whether the issue
7 was the filters or the migration resistance testing.

04:18:19

8 Correct?

9 A. That is correct.

10 Q. And what you discovered quickly was that there were values
11 below 50 millimeters of mercury when testing the filters
12 manufactured using the current supplier; right?

04:18:32

13 A. That is correct.

14 Q. So whether or not it came from Starguide, whether or not
15 it came from the current supplier, below 50 millimeters of
16 mercury?

04:18:46

17 A. That is correct.

18 Q. And this points to the fact that there is an issue with
19 migration resistance testing. That's what it says; right?

20 A. Yep, that's what it says.

04:19:00

21 Q. I'm sorry?

22 A. Yeah, that's exactly what it says.

23 Q. The conclusion was there must be something wrong with the
24 testing. There's not something wrong with our filters.

25 A. So prior to this report, we had just run an exhaustive

04:19:11

United States District Court

ALEX TESSEMER - Direct

1 test and they all passed, not the Starguide group wasn't
2 included in that but the group with the other wire that we got
3 manufactured.

04:19:15

4 And so I was trying to understand what was going on
5 because why had it passed in the previous report and not now.
6 So I was concluding, hey, is there something wrong with the
7 test, how it's set up? There's a lot of variability in the
8 whole test apparatus.

04:19:28

9 THE COURT: Mr. Lopez, we're at 4:20 so I think we
10 need to break at this point.

04:19:45

11 Ladies and gentlemen, I've got 4:30 hearings so we
12 need to break today at 4:20. We'll plan to start tomorrow at 9
13 o'clock. Please remember not to discuss the case or do any
14 research and we'll see you in the morning. Thank you.

15 (Jury departs at 4:20.)

04:20:00

16 THE COURT: Counsel, for your information,
17 plaintiffs, as of the end of the day, have used six hours and
18 17 minutes. Defendants have used two hours and nine minutes.

19 MR. O'CONNOR: Excuse me, Your Honor. Did you split
20 the time up in the depositions?

04:22:26

21 THE COURT: No, I did not.

22 MR. O'CONNOR: We need to do that.

23 And the other thing we would ask, Your Honor, you
24 know, when we play the deposition, the agreement is that we're
25 playing both sides in the case. So in fairness, we think that

04:22:36

United States District Court

ALEX TESSEMER - Direct

1 the jury should be told that this is both parties' submission
2 of the deposition as opposed to the plaintiff's.

04:22:39

3 THE COURT: Why should they be told that? It's the
4 witness's testimony.

5 MR. O'CONNOR: Well, because we're putting on theirs
6 at the same time, but we do need to make sure that the time is
7 counted.

04:22:51

8 THE COURT: How do you --

9 MR. LOPEZ: We have a run that actually keeps track
10 of the time.

04:23:02

11 THE COURT: You can give me the time and I'll make an
12 adjustment.

13 MS. HELM: Your Honor, I would love to see the run
14 time.

15 THE COURT: Why don't you talk about that and see if
16 you can agree on the adjustment that needs to be made, but I
17 attributed all of that depo time to you so get me that
18 adjustment.

04:23:09

19 MR. LOPEZ: We will.

20 (Whereupon, these proceedings recessed at 4:24 p.m.)

04:23:55

21 * * * * *

ALEX TESSEMER - Direct

C E R T I F I C A T E

04:23:55

I, ELAINE M. CROPPER, do hereby certify that I am
duly appointed and qualified to act as Official Court Reporter
for the United States District Court for the District of
Arizona.

04:23:55

I FURTHER CERTIFY that the foregoing pages constitute
a full, true, and accurate transcript of all of that portion of
the proceedings contained herein, had in the above-entitled
cause on the date specified therein, and that said transcript
was prepared under my direction and control, and to the best of
my ability.

04:23:55

DATED at Phoenix, Arizona, this 16th day of March,
2018.

04:23:55

s/Elaine M. Cropper

04:23:55

Elaine M. Cropper

United States District Court